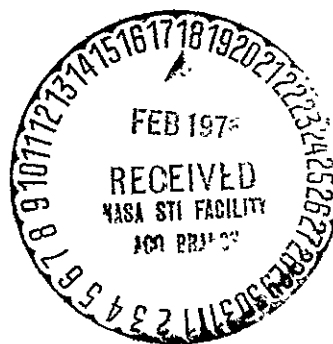


STUDY OF AEROSPACE TECHNOLOGY UTILIZATION
in the
CIVILIAN BIOMEDICAL FIELD

FINAL REPORT

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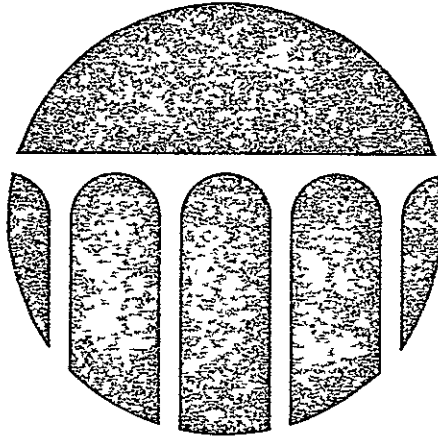


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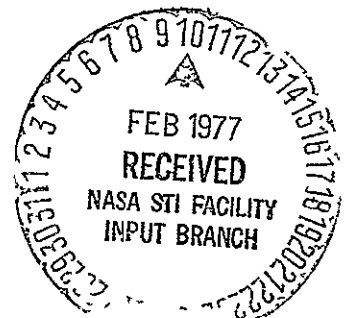
FINAL REPORT



CONTRACT NO. NASW - 2052

Committee on the Interplay of Engineering
with Biology and Medicine

NATIONAL ACADEMY OF ENGINEERING
Washington, D. C.



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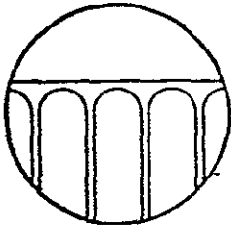
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The National Academy of Engineering was established in December, 1964. The Academy is independent and autonomous in its organization and election of members, and shares in the responsibility given the National Academy of Sciences under its congressional act of incorporation to advise the federal government, upon request, in all areas of science and engineering.

The National Academy of Engineering, aware of its responsibilities to the government, the engineering community, and the nation as a whole, is pledged:

1. To provide means of assessing the constantly changing needs of the nation and the technical resources that can and should be applied to them; to sponsor programs aimed at meeting these needs; and to encourage such engineering research as may be advisable in the national interest.
2. To explore means of promoting cooperation in engineering in the United States and abroad, with a view to securing concentration on problems significant to society and encouraging research and development aimed at meeting them.
3. To advise the Congress and the executive branch of the government, whenever called upon by any department or agency thereof, on matters of national import pertinent to engineering.
4. To cooperate with the National Academy of Sciences on matters involving both science and engineering.
5. To serve the nation in other respects in connection with significant problems in engineering and technology.
6. To recognize in an appropriate manner outstanding contributions to the nation by leading engineers.

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SUPPLEMENT I

Report of the Ad Hoc Group on Pulmonary Care

SUPPLEMENT II

Report of the Ad Hoc Group on Cardiovascular Care

SUPPLEMENT III

Emergency Medical Communications

FOREWORD

Various investigators have examined the process of transferring technology from industrial R&D laboratories and other nongovernmental sources into general utilization. They have defined a complex of "Push" factors such as availability of ideas, capability, materials, financing and other resources and "Pull" factors such as available desires and needs, well aggregated market, distribution capability and the like. When these factors combine favorably and indicate the prospect of profit without undue risk, the process moves forward and technology is utilized, or more simply, innovation occurs.

The monetary and manpower resources required for the process are often underestimated, especially the rather steep increase in resources required when the laboratory phase is completed and production begins. Likewise the brokerage problem involved in inducing the many separate entities to work together if a common, general program or production is to result, is only beginning to be understood.

There is increasing national concern that much technology useful to the general public lies dormant in the R&D laboratories of the Federal high technology agencies. Several of the agencies have begun programs to bring this technology into use and there is increasing activity in technology transfer/utilization, both to accomplish it and to find how to accomplish it more effectively.

At the request of the National Aeronautics and Space Administration, the Committee on the Interplay of Engineering with Biology and Medicine (CIEBM) of the National Academy of Engineering undertook a review of aerospace technology utilization in the civilian biomedical field. The committee worked with NASA in bringing together multi-disciplinary teams to identify opportunities for the use of aerospace technology in medicine and to pursue those opportunities sufficiently to validate the idea and bring the system to a state of development that would assure that utilization could result. This

has been accomplished although with some success as well as some frustration as the realities of the process were encountered.

The process of transferring space technology developments from research to user in the civilian biomedical field is complicated to a high degree by the fact that there is not a single user or aggregated groups of users already set up to make such technological transfers. The complexity of transferring technology into the biomedical field is attested to by the fact that a number of manufacturing companies have experienced substantial difficulties in the biomedical area, although these same companies have demonstrated technical effectiveness and commercial viability in many other areas.

There appear to be at least four primary entities engaged in the transfer of NASA technology into the biomedical field.

- (1) The space-connected laboratory which has developed the basic technology;
- (2) The set of several industrial manufacturing companies that would be required to put component pieces together in the biomedical area in which the technological advance finds specific practical application,
- (3) The government laboratories associated with the National Institutes of Health as well as possibly other public agencies that would have interests, financial resources, and public responsibilities in providing components of the health care system, and
- (4) The doctors and the hospitals who have professional responsibilities for the system which delivers the health care itself.

This group of potential partners has had little previous experience in working together. Moreover, their differing styles of activity and their varied responsibilities in other fields make it quite unlikely that they would work from the start as a smoothly functioning team. Thus the problem of management of the transfer process in this rather complicated system of actors requires the heretofore unestablished process of exploration and brokerage.

The efforts of the CIEBM will no doubt contribute in some measure to progress in the study of the highly complex issues of utilization of aerospace technology in the civilian biomedical field. It is our hope that other Academy efforts, recently initiated, will further add to our knowledge and understanding of technology transfer and utilization. At the request of the National Science Foundation, the Academy in 1972 established a committee to study selected aspects of its Experimental R&D Incentives Program in order to evaluate its prospects for success and the potential for undesirable side effects of experimental incentives under consideration by the Foundation. Further, in 1973 the National Science Foundation requested the Academy to establish an ad hoc Committee on Technology Transfer and Utilization to undertake a study of government agency programs which have the goal of stimulating the transfer of technology into the public and private sectors. This second study will examine and evaluate the experiences of the selected government agencies and will provide alternative policies that might be considered by the National Science Foundation in the testing of its Experimental Research and Development Incentives Program.

W. Robert Marshall, Chairman
Committee on the Interplay of
Engineering with Biology and
Medicine

Washington, D C.
November 7, 1973

PREFACE

The National Academy of Engineering in its role as an advisor to Congress and Federal agencies, has placed responsibility for studies of the engineering-medicine interface within its Committee on the Interplay of Engineering with Biology and Medicine. Under this parent committee is a subcommittee which is concerned with the transfer of technology and expertise from within Federal agencies (e.g., NASA) to the civilian sector of health care delivery. Chaired by Dr. David D. Rutstein, Harvard Medical School, this Subcommittee on Technology and Systems Transfer was established to analyze, promote, and enhance the application of technology within Federal Government agency programs to solutions of problems in civilian health care.

The purpose of this report is to document the activity accomplished during the past three years on NASA Contract No. NASW-2052. Under this agreement a program of work was set forth as follows:

"A. Identify Aerospace Engineering Technology which appears relevant to specific technological requirements in the biomedical field.

B. Relate the biomedical requirements to identified engineering technology in such manner as to facilitate follow-on activities by the NASA at its option.

C. When requested by the NASA, provide expert professional advice concerning initiation of specific projects identified in activities under paragraph (B) above.

D. Identify and recommend to the NASA such interfaces with mission oriented organizations as will contribute to furthering the goal of transferring engineering technology to biomedicine on a continuing basis.

In addition, the Contractor shall be responsible for keeping apprised of related on-going activities within the NASA sponsored Biomedical Application Team Program to ensure accomplishment of complementary efforts."

As stated above, the Committee was charged with the responsibility of identifying specific NASA technology that could be applied to health care and to encourage and develop the means by which this technology could be transferred. During the three years in which the Committee undertook this work, it was a unique position to observe the characteristics of the transfer process and, in particular, the methods used by the space agency in its technology utilization (TU) program. It was natural that in addition to formulating recommendations concerning specific technologies, the Committee would arrive at some conclusions and develop some recommendations concerning the organization and current administration of the NASA TU effort. Thus this report considers issues related to the transfer process and also summarizes Committee activities in five selected fields of health care that were addressed during the three-year study.

The Academy and the Committee were indeed fortunate to have the services of the Subcommittee, chaired by Dr. Rutstein and the three Ad Hoc Groups on Pulmonary care, Cardiovascular Care and Remote Diagnosis and Treatment, chaired by Subcommittee members Drs. Buckles, Mylrea, Buskirk and Drinker. Without their diligent effort, the task could not have been completed, and we deeply appreciate their contributions.

The work of the Committee and Subcommittee has been greatly assisted by the CIEBM staff. Charles W. Garrett (Executive Secretary) and Lonnie C. Von Renner (Professional Staff Assistant) have been with the project since its inception, the latter having the Subcommittee work as his primary responsibility. His dedication and creativity were direct influences on the course of the study. Ms. Jean Ruffin (Research Associate) and Abraham Leventhal (Professional Assistant) were assigned to the project during portions of its conduct, as were Ms. Dorothy B. Campbell (Administrative Assistant), Ms. Marianna Shepard (Administrative Secretary), Ms. Ernestine Pierce (Secretary), Ms. Mary Alice McDonough (Secretary) and Ms. Mary Gordon (Secretary). Their efforts are most gratefully acknowledged by the committee.

INTRODUCTION

INTRODUCTION

The overall objective of the Academy effort was to study means by which NASA capabilities may be more effectively utilized to improve the delivery of health care in this country. The study rested upon three assumptions:

- (1) Health care delivery could benefit from a more extensive application of technology.
- (2) NASA, through the performance of its primary mission, has developed a far-ranging and perhaps unique familiarity with certain technological areas which are related to current needs in the medical profession.
- (3) Current efforts by NASA to contribute in health care delivery can be improved upon.

These operating assumptions were, in the view of this Committee, verified during the course of the Committee's work. _____

The NASA Technology Utilization Program

The technology transfer process involves information, devices, technological processes, and technological rationales for problem solving. The latter category includes such things as systems analysis and management and evaluation techniques, that is, schemes for problem definition and for organizing and managing the resources used in developing appropriate solutions.

Historically, there have been two approaches used in NASA's technology utilization program. The first has been characterized as solutions looking for problems. Technological solutions abound within NASA's technological base. In the process of solutions looking for problems, solutions are advertised on a very broad basis in the hope that those having

a problem will find an applicable solution. The widespread dissemination of NASA Tech Briefs is an example of this process. Tech Briefs, at most a few pages in length, describe instruments, devices or processes resident within the NASA program. The hope is that somebody with a problem will happen upon the solution by perusing Tech Briefs. Other examples include the Scientific and Technical Aerospace Reports (STAR), the International Aerospace Abstracts (IAA) and the Regional Dissemination Centers, all of which are designed to make NASA solutions readily available; those with problems must come to find them.

The other major approach to transfer is, of course, that of identifying problems first and then looking for the solutions. NASA also has utilized this approach. It has established biomedical application teams, or BATeams, at a few nonprofit research centers around the United States. Staff members of the BATeams attempt to locate problems by talking with people involved in biological and medical research and health care delivery and by continual study of health care delivery processes. Once a BATeam has identified a problem, it uses its knowledge of the NASA technological repertoire to aid in working toward a solution. Early in the program (circa 1969) BATeams often only provided information to the user. Of late, the emphasis has switched to one of providing hardware, including some development when required, to achieve a transfer. NASA also has used other institutions such as university teams (and the Academy), under contract, to identify problems and match NASA technology to potential solutions.

There are several characteristics of the BATeam approach which merit consideration. BATeams attempt to assess the importance of an espoused problem by making estimates of the size of the national patient population that could be benefited by its solution. This estimate is used to judge the merit of supporting the transfer with additional investment of NASA resources. In the analysis, however, certain key questions are not addressed: Will the cost of the solution be acceptable to the health care providers? How many units can be sold for the estimated price? Is industry prepared to take the end product of the NASA development and carry it through to production with an effective sales and distribution program? The lack of an adequate market survey may mislead or impede private companies which might otherwise step forward to manufacture the device or process. The role of industry

is critical to achieving most transfers in any meaningful sense. But the road must be well paved or the risks to private capital will outweigh the speculative promise of profits. Thus, BATEam efforts could be considerably enhanced if sound marketing data were also generated.

A second characteristic of the approach is that the time frame of BATEam transfer operations is generally short, on the order of a few months or less. Third, for the most part, little expenditure of funds other than that required to operate the BATEams has been involved. \$5,000 - \$10,000 per transfer is a typical investment for hardware and development.

NASA has also supported hardware and software development both by contributing NASA personnel time and by contract with NASA vendors for particularly promising devices or systems. These efforts also are of a relatively small scale, generally in the \$25,000 - \$50,000 class and one year or so in duration.

Each of the above techniques is a legitimate technology transfer operation, and each has its place in a comprehensive technology transfer program of an agency such as NASA.

An Expanded Transfer Concept

It was the Committee's view that there is another technology transfer process which has not been utilized to date and it is this process which our Committee attempted to develop by means of demonstrations. The concept may be summarized as follows. In the area of health care delivery, there are rather significant and somewhat universal problems faced by those providing services and functions. Some of these problems may be alleviated by an appropriate use of technology. Further, if the problem is of sufficient impact, it may well prove worthwhile to expend considerable funds and a considerable length of time to accomplish the transfer of the technology; perhaps \$200,000 or more expended over several years of development, clinical trials and ultimate deployment.

Thus the study focused in part on: (1) identifying some significant problems in health care delivery rather universally faced by the medical profession that could be alleviated

by NASA technology applications; (2) identifying the specific technology and delineating the specifications for further development and evaluation, and (3) developing the institutional relationships and collaboration required to accomplish that development and evaluation process.

The Committee was faced with having to select, rather arbitrarily, a few medical areas for concentrated study to demonstrate the expanded transfer concept. It also, of course, desired to maximize the probability that relevant NASA technology could be identified once significant medical problems were defined. Because of its outstanding expertise in instrumentation, the Committee felt that NASA technology held promise for at least two important medical applications. (1) the substitution of fast and precise physical measurements for slower and less accurate chemical determinations that are now a standard part of medical practice, and (2) the substitution of non-invasive measurements (using NASA developments in transducer technology) for invasive patient measurements.

Chosen for intensive study were the fields of acute pulmonary care and cardiovascular care. Patients in acute respiratory or cardiac distress are often subjected to the types of measurements referred to above. These two areas share the characteristics of being a part of common medical practice of long standing. In contrast and as a third area of study, the Committee chose a new, emerging concept in medical practice as yet only explored in a handful of isolated research and demonstration projects. This is the delivery of health care at a distance -- remote health care -- in which the practitioner is physically separated from the patient, connected by communications systems (e. g. voice and television channels). The potential of NASA technology for such systems is obvious, the Committee endeavored to determine what the NASA contribution might be to their development.

At the request of the agency, the last fifteen months of the study turned toward an extensive examination of the field of emergency medical services with the same objective in mind. What might be NASA's capability to aid in the current national thrust to improve the quality of emergency health care?

Finally, the Committee identified and pursued the application of one unique system -- a urine bacteria detection

method -- to further demonstrate the concept of long-term development and funding of potentially very useful medical technology.

The pulmonary, cardiovascular, remote care, and emergency medical services projects revealed serious institutional impediments to the technology transfer process and, although varying degrees of progress were made on them, it cannot be claimed that any has yet yielded effective fruit as far as completing a meaningful transfer is concerned. The urine bacteria detector project progressed, with great difficulty, to the point where further Committee involvement would not be required.

In the pursuit of all of these efforts, much was learned about the process of technology transfer from a federal technological agency to civilian health care delivery. Here, perhaps, lies the ultimate value of the Academy's involvement, for institutional impediments are man-made. With courage, motivation, cooperation and rational management, they can be removed. Considerations of this nature are discussed in the next section of the report, with the hope that the managers of both the space agency and mission-oriented health agencies can derive some useful new concepts and procedures to accelerate and enhance the natural process of technology transfer.

Subsequent sections describe the course of the Committee's specific efforts in explicative fashion. Various Appendixes and supplements further summarize Committee findings and document Committee activities during the three-year contract period.

THE TECHNOLOGY TRANSFER PROCESS
AND NASA TECHNOLOGY UTILIZATION MANAGEMENT

THE TECHNOLOGY TRANSFER PROCESS AND NASA TECHNOLOGY UTILIZATION MANAGEMENT

It has always been the hope of the Committee that in addition to revealing some generic characteristics of the technology transfer process, this study would serve to strengthen NASA's technology utilization (TU) program by both demonstrating an expanded, workable transfer concept and by establishing collaborative relationships between the space agency and mission-oriented health agencies.

The Committee has not been entirely successful in fulfilling these latter two objectives. It is felt that the problems encountered together with some recommendations for their alleviation would be of interest to NASA, to other technologically rich federal agencies concerned with technology utilization, and to the mission-oriented federal health agencies with which the Committee has interacted.

It should be understood that the comments in this section are not intended to convey criticism. Rather, they are included solely for constructive purposes for consideration by NASA management as it strives to improve the NASA TU program. Further, it is recognized that the experiences upon which these conclusions and recommendations are based were those of our Committee, Subcommittee, Ad Hoc Groups and staff. It is possible, although the Committee doubts it, that these experiences were unique and peculiar and that the problems encountered (to which the recommendations are addressed) are not, in fact, prevalent.

The Technological Agent and the User Agent

Essential, in the Committee's view, to effective technology transfer in the health care field is the proper relationship between the user community and the technological source. In the realm of this study, the user community was the health care delivery system and the technological source was the technology resident within NASA and its contractors. Both the user and the technological source and a mission-oriented health agency (e.g., the Health Services and Mental Health Administration) or other institution (e.g., American Hospital Association) was to be

the agent of the user. It is our Committee's opinion that neither agent can conduct the transfer process unilaterally. Rather, both agents must be intimately involved in the transfer process from beginning to end, particularly if the transfer requires an expenditure of a considerable amount of funds and resources to bring about a solution.

The first step in the technology transfer process is problem definition. This requires the insights, knowledge, and expertise of the medical scientist and medical practitioner working with the user and the technological agent. During the problem definition phase, although the technological agent should play an important role, the user agent must take the lead. NASA does not hold a charter to operate unilaterally in the civilian health field, nor can it be expected to identify the existing problems and have broad knowledge of the characteristics of the real world of health care delivery. This can, however, be provided by a mission-oriented health agency or other broad representative body acting as the user's agent. The next step of the transfer process involves the searching for technological components which will lead toward a solution. Here the technological agent must assume the lead. Once these technological elements for a solution are identified, there follow development, test and evaluation conducted both in the engineering laboratory and in the clinical environment. Here both the technological agent and the user agent must work collaboratively to insure that the best technological solution is provided and to insure that the clinical objectives are met. Finally, once a solution has been evaluated and found to be useful, there remains perhaps the most important function of all, that is, the injection of the solution into the user community so that there remains not a one-of-a-kind system being operated as prototype somewhere, but rather a system which becomes an accepted component of the armamentarium of health care delivery.

This latter task falls to two groups. First is the user agent, for it has a far greater ability to influence the ultimate users and carry the results to the delivery system at large than does the technological agent. The mission-oriented federal health agency often has leverage through the use of funding control, ability to promulgate certain rules and regulations, and influence upon health operations and legislation not available to the technological agent to further this transfer process. The other type of user agent (e.g., American Hospital Association), while not a federal agency, is a body that has direct influence upon the user community and therefore is in an excellent position to serve as a distributor of the new technology application.

In the ultimate, it is the degree to which the solution is adopted throughout the user community that measures the success of the transfer process. Of critical importance, therefore, is the conviction of the user agent that the device, process or technique proposed for transfer is sound and worth distributing. This conviction can best be achieved when the user agent participates with the technological developer throughout the transfer process, thus identifying the resulting product as being as much his as that of the technological agent. It is a rare case, indeed, where the technological agent can unilaterally choose the problem, develop the technology, create the solution (e.g., a new "black box") and then create a strong motivation in the user agent to serve as the distributor.

The second necessary partner in the widespread transfer of technology is industry. Here, as elsewhere in the overall process, there have been problems. The NAE has considered this question in some detail. Among the chief conclusions derived from an in-depth survey of fifty companies involved in biomedical engineering were these: ¹

1. That industry faces several problems in becoming active, including lack of an identifiable market of sufficient size for new medical instruments and fear of legal repercussions which could result from misjudgment in an endeavor directly influencing human life.
2. That there is no informed consumer demand for better or new products or services.
3. That there is an absence of competitive cost pressures and incentives for cost reduction by new technology because of the historical development of hospitals along philanthropic lines and the presence of third party insurance companies to pay the bills.

¹ Committee on the Interplay of Engineering with Biology and Medicine, An Assessment of Industrial Activity in the Field of Biomedical Engineering. National Academy of Engineering, Washington, D. C. (1971).

The Committee believes that by engaging NASA, HEW, and private industry in a cooperative program, such as the one attempted in pulmonary care, some of these problems will be alleviated promptly. Reducing the remaining impediments, caused by uncoordinated methods of health care delivery in this country, must await other, bolder attacks.

The Lending of Intellect

In most attempts used so far to transfer technology and, indeed, in the model proposed above, there remains a delineation of two groups, the technological group and the user group. The process involves the transfer of information and hardware between these groups, collaborative activity between them, and people with experience in both. The Committee proposes that an efficient mechanism to bring this about is the transfer not only of information hardware and software but also the transfer of people; that is, assigning technologists well-versed in the technology deemed transferable to full-time, albeit temporary, positions in organizations of the user community faced with solving user problems. For example, NASA engineers could be assigned full-time duty in a hospital, a city communications department or a university project developing prosthetics for the handicapped. This could constitute a technological agent's sole contribution to a specific transfer process, the lending of intellect. When the task is complete, such persons could return to their regular duties. Not only would the user community benefit from such an arrangement; cross-fertilization would occur and the technologist returning to the space agency would bring a broader outlook and, perhaps, even new technological concepts that would accrue to NASA's benefit--technology transfer can be a two-way street.

Technology Utilization Management within NASA

The Committee experiences lead it to offer several recommendations which could enhance the technology utilization (TU) program within NASA.

1. Assignment of People. It was suggested that one effective means of transferring technology is the lending of intellect--the assignment of NASA employees to operate within the community that will be the ultimate recipient of the transfer. Because of current administrative constraints in the agency, this is very difficult to accomplish. It has been done in only a few selected instances such as assignments made under the

Federal Intergovernmental Personnel Act of 1970. It is far easier for NASA to contract for a \$75,000 technology transfer hardware development than it is to obtain approval to "lend" a \$25,000 per year salaried engineer who, working in the user's community for a year or two, could accomplish equivalent, if not more effective, transfer functions. NASA could strengthen its TU program considerably if constraints to assigning personnel to extra-NASA institutions and to internal technology utilization projects were reduced.

2. Strengthening Interagency Collaboration.

Some problems that developed in this area came as a surprise to the Committee. In developing the contractual agreement between the Academy and the Agency to conduct this study, NASA consistently emphasized its desire for aid in developing mutual, collaborative programs between NASA and mission-oriented health agencies. Perhaps naively, the Committee did not anticipate serious difficulty. Yet in attempting to accomplish that end, the Committee often was frustrated by a seeming reluctance on the part of agencies to cooperate. This reluctance was found in the health agencies as well as within NASA. Some examples are in order.

In the pulmonary care project, the Committee has yet to be successful in developing funding support in either the National Institutes of Health (NIH) or the Health Services and Mental Health Administration (HSMHA). In this case, the reluctance came from those agencies, although obtaining a definite commitment from NASA as to what it would contribute in the form of hardware and engineering expertise has also been difficult. Having that information might have made approaches to the health agency more effective.

A lesson learned from that experience is the desirability of coordinating the offering of technology with the current priorities and thrusts of the health agencies. When the technology offered matches the user agent's needs, the probability of negotiating a joint program is greatly increased. Further, the health agency's priorities and thrusts should be excellent indicators of significant current problems demanding attention.

At the height of the pulmonary care project, for example, neither NIH nor HSMHA was placing heavy emphasis on pulmonary care hardware development; in fact, the National Heart and Lung Institute (NHLI) initiated a study of its own on technology needs in pulmonary care. Until that effort is complete and the agency moves toward implementation of its recommendations, NHLI is not very inclined to provide any substantial support.

In its health care technology transfer program, NASA should maintain close contact with the mission-oriented health agencies and other user institutions and stay apprised of continually changing and emerging program thrusts and priorities. Further, when a collaborative transfer project is undertaken, a willingness on the part of all agencies involved to share management prerogatives as well as resources is a necessity.

3. Internal Management Control of Technology Utilization Projects. Since the Office of Technology Utilization is a staff office in the agency while the personnel in the NASA Field Centers conducting TU programs are in line management, the Office of Technology Utilization has little management control of the projects it funds through or in the Field Centers.

The NASA commitment to technology utilization and transfer would be considerably strengthened if means were developed by top management that would permit direct headquarters management control of technology utilization projects originating in and funded by the Office of Technology Utilization.

A Closing Statement

The national technological resources could be beneficially exploited in a way that has gone heretofore untapped. NASA, other agencies of government and the private sector can all assist toward that end. Required are.

1. An expansion of the concept of technology transfer to include large, more imaginative development, evaluation and deployment schemes addressed to significant and universal problems.

2. True interagency and inter-institutional collaboration from problem definition to user acceptance.
3. A recognition of the needs and capability of American industry.

PULMONARY CARE

PULMONARY CARE

Background

As one of its projects to demonstrate a long-term collaborative technology transfer, the CIEBM Subcommittee on Technology and Systems Transfer selected the area of pulmonary care for investigation.* An ad hoc group[†] of national experts in pulmonary care was formed to identify and specify urgent problems in managing patients with acute respiratory difficulties and to explore ways in which NASA technology might be applied toward their solution. Members of the CIEBM Subcommittee on Technology and Systems Transfer and persons knowledgeable in NASA's technology base were also represented in the Ad Hoc Group on Pulmonary Care.

After extensive study, the Ad Hoc Group documented its efforts in a report (Supplement I) to the Subcommittee. The report concluded:

"The most promising area of potential utilization of space and defense technology in pulmonary care appears to lie in diagnostic measurement and monitoring, rather than in therapeutics."

It went on to make five recommendations of which the first dealt with measurements in intensive pulmonary care.

"We recommend that NASA support and cooperate in programs of advanced development of an integrated system for continuous breath-by-breath analysis of respiratory flows and gas composition, as well as for blood gas measurement."

* The rationale for this choice is described in the Introduction.

[†] The membership of all Ad Hoc Groups is listed in Appendix A.

Detailed discussion in the report augmented this generic recommendation. Key was a proposal to develop and clinically evaluate a mass spectrometer-respiratory flowmeter-minicomputer system that could provide fast and reliable respiratory and blood gas measurements, preferably on a number of patients. As of August, 1971, commercial concerns had not evidenced serious activity in such a development.

The mass spectrometer state-of-the-art at the time caused the Ad Hoc Group to recommend the magnetic sector type over the quadrupole type because of the better stability and reliability of the former. In particular, the magnetic sector spectrometer developed by Perkin-Elmer for NASA was deemed to be directly applicable to the system proposed.

The Ad Hoc Group could not recommend any commercial respiratory flowmeter, finding serious difficulties with those in current use. It recommended that NASA undertake the production of a simple flowmeter which Bowles Fluidics, Inc., had developed for aeronautical research purposes and which appeared very promising for the pulmonary measurement application. The space agency implemented this recommendation and Bowles Fluidics, Inc., is presently manufacturing a flowmeter to be used in a prototype system. NASA, through the Johnson Space Center, is also supporting the development of a flowmeter by Beckman Instruments, Inc.

During the period from August, 1971, to June, 1972, the Subcommittee attempted to assist NASA in implementing the recommendation quoted above. It was hoped that a joint development and evaluation project between NASA and a mission-oriented health agency could be initiated; however, such has not materialized. Although extensive discussions took place, neither the National Heart and Lung Institute (NHLI) in the National Institutes of Health nor the National Center for Health Services Research and Development in the Health Services and Mental Health Administration (HSMHA) could be sufficiently encouraged to fund the clinical effort required. NASA was willing at one time to support such a joint effort by providing a spectrometer, flowmeter and engineering expertise to such a project and has, on its own, funded the construction of the promising flowmeter prototype. But without support and direction from a health agency, the program could not be carried to the point hoped for by the Committee during the tenure of its involvement.

In the process, the Ad Hoc Group report and supporting documentation were transmitted to commercial producers of medical mass spectrometers and to respiratory research centers. The Committee has observed several changes in their approaches as a result, which suggests that the effort has not been completely unsuccessful.

Further, the Subcommittee located several clinical teams* willing and competent to undertake the clinical development task. One (MGH) prepared a detailed proposal to support the clinical effort and development required. The concept was that NASA would supply a NASA-developed mass spectrometer, the Bowles flowmeter (also possibly a minicomputer) and engineering support to the clinical team whose time and other costs would be borne by the mission-oriented health agency. However, as noted above, the Subcommittee was unsuccessful in its quest, and by June, 1972, no health agency support was forthcoming.

While the Subcommittee was pursuing its deliberations with the health agency, the year from August, 1971, also saw increased industrial interest in mass spectrometer applications to pulmonary measurements. This can partially be attributed to the Subcommittee discussions with industry. Perkin-Elmer introduced a commercial equivalent of its NASA-funded magnetic sector spectrometer in the fall of 1971. The Perkin-Elmer Model MGA-1100 Medical Gas Analyzer, however, did not incorporate a flowmeter or computer as standard equipment. Automated Medical Systems of Minneapolis announced a quadrupole spectrometer-flowmeter-computer package in early 1972. The University of Maryland Center for the Study of Trauma reported a multi-patient mass spectrometer-respiratory monitor in daily use in its trauma intensive care ward. These events caused the Subcommittee to re-examine the status of such systems, and to determine the state-of-the-art as of fall, 1972.

* Massachusetts General Hospital, Boston; Latter Day Saints Hospital, Salt Lake City; University of Maryland, Baltimore; University of Minnesota, Minneapolis.

Present State-of-the-Art

The state-of-the-art review was performed by addressing a written inquiry to every known manufacturer or distributor of mass spectrometers used for medical purposes. Replies were received from twelve, of whom seven were found to offer some type of relevant system. Table I summarizes the data collected.

Site visits were made to Minneapolis to investigate the Automated Medical Systems development and the Centronic (British) device, and to the University of Maryland to examine the on-line Scientific Research Instruments machine used in the Center for the Study of Trauma. A summary of these visits is included as Appendix B.

Conclusions

The conclusions reached by the Ad Hoc Group as a result of these activities are as follows:

1. Further refinements by developers of quadrupole spectrometers have brought the stability and reliability of these devices in line with those of the magnetic sector type of machine. Either type appears applicable for clinical pulmonary measurement purposes.
2. The commercially available Fleisch pneumotachograph, though unsatisfactory, still is the flowmeter used in most systems, including that of the University of Maryland. A Thermo-systems hot film unidirectional flowmeter, also judged unsatisfactory by the Ad Hoc Group, is used by Automated Medical Systems. The Statham ultrasonic flowmeter, though available commercially, has not been refined to remove inaccuracies caused by changes in sound velocity as the air stream gas concentration and water vapor changes. (The University of Maryland has an on-going program to solve these problems with the Statham unit.) Thus the flowmeter problem originally identified remains, and continuation of the development of the Bowles Fluidic device is justified.

Manufacturer	Model	Spectrometer Type	Respiratory Gas Use	Blood Gas Use	Effective Mass Range (AMU)	No. of Channels	Multiple Inlets	Flowmeter	Computer	Notes
Automated Medical Systems	PFA-5	Quad	Y	Y	2-100	5	Y	Hot Wire or Hot Film	Analog Available as Standard Equipment	Digital Computer added in prototype test (U. of Minn.)
Bendix	MA-1	TOF	Y	Y	1-500	Up to 8	?	Not Avail. as Std. Eqt.	Not Available as Std. Eqt.	
Centronic (Univ. Hosp. Services, Inc.)	Mark I	Quad	Y	Y	2 - ?	8	Und. Dev.	Not Avail. as Std. Eqt.	Analog & Digital Modules under Development	
Perkin-Elmer	MGA-1100	MS	Y	N	4-120	To 6	To 4	Not Avail. as Std. Eqt.	Not Available as Std. Eqt.	Flowmeter & Computer added in Prototype development (LDS, J. West)
Scientific Research Instruments	MS - 8	MS	Y	Y	4-132	To 6	To 12	Not Avail. as Std. Eqt.	Not Available as Std. Eqt.	Flowmeter & Computer added in prototype development (U. of Md.)
Vacumetrics	MMS-100	Quad	Y	Y	1-400	8	Y	Not Avail. as Standard Equipment	Not Available as Standard Equipment	
	RMS-3	MS	Y	N	4-100	4	N			
	BG - 1	MS	N	Y	4-100	4	Y			
	RMS-BG	MS	Y	Y	4-100	6	Y			
Varian	M-3	MS	Y	N	2-300	4	N	Not Avail. as Std. Eqt.	Not Available as Std. Eqt.	

Spectrometer Type: Quad - quadrupole
 MS - magnetic sector
 TOF - time-of-flight

3. Automated Medical Systems and Universal Hospital Services, Inc., both have incorporated computers into prototype units. In addition, the University of Maryland system makes excellent use of a programmed Wang desk calculator for system control and data reduction purposes. The concept of using a computer in the system has been usefully demonstrated. No standard commercially available system uses a computer as a routine, non-custom option, however.

Summary and Final Recommendation

Several industrial firms, many of which have had NASA support for basic development, have developed clinically applicable medical mass spectrometers which are at the stage where clinical testing is now appropriate. If a NASA-supported transfer of technology in the area of respiratory monitoring is feasible, support must now be obtained and directed at the integration of the mass spectrometer-flowmeter-computer system together with technical support in areas which are still lagging in technology, such as the flowmeter.

Of particular need, once the technological obstacles have been overcome, is support for clinically-based personnel to implement and use the respiratory monitoring system in the clinical setting. This latter aspect, the support of clinically-based personnel, is absolutely essential if this technology is to be delivered to the broad medical community in the form of a truly workable system that has demonstrated its usefulness in patient care. In the view of the Ad Hoc Group, such utility remains to be evaluated and documented.

It should be emphasized that further development should not be performed by those unfamiliar with the clinical situations; the problem is now at the level where dependence on people familiar both with the instrumentation and with the clinical problem is required. Therefore, support should be directed to groups such as the University of Minnesota-AMS team and the University of Maryland Center for the Study of Trauma. These teams are engaged in these problems, familiar with them, and actively seeking solutions.

Committee efforts have stalled because financial support was not obtained from any of the health agencies. Whether or not total financial support should come from NASA is an administrative determination not deemed to be within the purview of this Committee. No recommendations are offered.

There are several specific technological needs which also can be identified. First, the work on flowmeter development by Bowles at the present time looks at least as promising, from the practical standpoint, as any. The Beckman development, while theoretically appealing and possibly of relatively simple application in areas such as exercise physiology, needs to be extensively redesigned and proven before it could be applicable for respiratory monitoring of the acutely ill patient. The Statham ultrasonic unit, while also promising, has yet to have critical problems in accuracy resolved, the units under trial at the University of Maryland have been extensively altered in an in-house effort to solve these difficulties. In electronics development, the need defined by Dr. Mosharrafa* of Automated Medical Systems Company for a high gain, stable, electron multiplier should be pursued. This may well be a project to which NASA is uniquely equipped to contribute. Nonetheless, the fundamental problem remains the support of clinically-based personnel to test the concepts outlined in the Pulmonary Care Report.

At the completion of its study, the report and summary statement have been provided again to NHLI and HSMHA with the hope that future progress might be made. Interestingly, during the course of the Committee study, NHLI contracted for a systems analysis study for respiratory devices. Both contract reports^{2, 3} made available to the Committee substantiate the need and desirability of the system proposed by the Subcommittee; one using the Ad Hoc Group report as a basis.

* See Appendix B.

² S. Kitrilakis, et al, Systems Analysis Study for Respiratory Devices, Final Report, Contract NIH-71-2430, Tecna Corporation, Emeryville, California (24 March 1972).

³ E. Z. Ratner and H. Weintrob, Systems Analysis Study for Respiratory Devices, Final Report, Contract NIH-71-2432, GEOMET, Inc., Rockville, Maryland (April, 1972).

CARDIOVASCULAR CARE

CARDIOVASCULAR CARE

Background

Using the same rationale that resulted in the selection of pulmonary care, a second area chosen for study was cardiovascular care. In identical fashion to that of the pulmonary care effort, an Ad Hoc Group^{*} documented its study in a report (Supplement II) to the Subcommittee which further studied and subsequently adopted the recommendations contained therein.

Although directing its attention specifically to cardiovascular care, the Ad Hoc Group also explored some generic issues of technology transfer in health care. In this regard, it concluded:

"... it is unrealistic to anticipate that major improvements in health care through technology transfer can be successful in less than five years."

The Group noted several areas related to and extending beyond cardiovascular care in which NASA could be of assistance:

1. Standardization of bioinstrumentation.
2. Extension of NASA quality control and preventive maintenance competence to biomedical instrumentation design and use in clinical environments.
3. Extension of NASA flight hardware research and development of non-invasive diagnostics to civilian needs.
4. Exploration of NASA capabilities in short-range communications for application to U. S. trauma victims.

* The membership of the Ad Hoc Group is listed in Appendix A.

5. Extension of NASA miniaturized mass spectrometers to on-line blood gas analysis in intensive care units.*

Hospital Instrumentation and Quality Control

As in the pulmonary study, one recommendation of the Cardiovascular Ad Hoc Group was selected for intensive further follow-on effort:

"We recommend that the technology of quality control and preventive maintenance be transferred to the biomedical community."

By choosing this topic, and in contrast to the pulmonary effort involving a hardware transfer, the demonstration project for cardiovascular care evolved into a software transfer, the transfer of management techniques in quality control and reliability.

Data on the NASA reliability and quality assurance program were obtained initially during a site visit to the Johnson Space Center in Houston and through the Reliability and Quality Assurance Office, NASA-Washington. Through this activity it was determined that NASA's capabilities lie mostly in the area of instrument design, taking into account such factors as hazard avoidance, failure mode effects and analysis, and standardization. All of this is needed in medical care and has resulted in much recent activity in hospital instrumentation and device safety. A related area of need is that of preventive maintenance programs within a hospital.

The program proposed by the Subcommittee was one in which reliability and quality assurance (R&QA) experts from NASA's Johnson Space Center in Houston would obtain first-hand information on a hospital's needs and on its peculiar

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* Note that in intensive care where cardiovascular and pulmonary care simultaneously are of importance, the Cardiovascular Ad Hoc Group supported the recommendations by the Pulmonary Care Ad Hoc Group concerning the applicability of mass spectrometers

operational environment by working in several civilian hospitals and in the Veterans Administration Hospital in Houston. The objective was to work in concert with the Veterans Administration and the American Hospital Association to examine the potential of developing procedure manuals and guidelines that would be useful to hospital administrators charged with introducing and managing hospital R&QA functions.

During separate meetings with the Veterans Administration (VA) and with the American Hospital Association (AHA) and its Houston affiliate, the Greater Houston Hospital Council, both groups agreed to cooperate by making hospital sites available.

The Johnson Space Center (JSC) subsequently let a \$25,000 contract to the Boeing Corporation to pursue the study. Boeing's R&QA experts stationed at JSC together with NASA personnel made frequent visits to the three civilian institutions and the VA hospital during the spring and summer of 1972. A draft report was prepared in October, 1972.

It was thought that the ultimate deployment of R&QA techniques to hospitals across the country would best be achieved through the VA and the AHA, two agencies having much influence upon, and responsibility for, hospital administration. Thus, it had been the intention of the Committee that the AHA and the VA would work closely with the NASA contractor and the Subcommittee throughout the project. Unfortunately, such was not to happen during the period of the NAE study. Although the October draft was shown to a Subcommittee and staff member, it has yet to be finalized and the Subcommittee has not had an opportunity to study the results. Nor, to the Committee's knowledge, has the VA or the AHA participated in its preparation.

The present status of the project is not clear. The Committee has been told that higher management in JSC directed a rewriting of the October draft and that the final report will be available in the near future.

Other Investigations

During its study, the Cardiovascular Care Ad Hoc Group and the Subcommittee investigated other pertinent NASA

technology applicable to cardiovascular disease diagnosis and treatment. The Group was particularly interested in non-invasive biomedical instrumentation developments at NASA's Ames Research Center and explored, with Ames personnel, the potential of several devices for early clinical application. Two devices which the Group felt had promise were an ultrasonic doppler blood flowmeter and an ultrasonic echographic system to measure left ventricular size.

The Group found that these devices were in early development and that much research remained to be done before clinical applicability could be assured. It also noted that the arrangements between Ames and the Stanford Medical School to pursue the needed research and development were appropriate and sound, when this research and development is further along, it would be worthwhile to reexamine the means to achieve a transfer since the potential of these devices in aiding civilian health care is large.

REMOTE DIAGNOSIS AND TREATMENT

REMOTE DIAGNOSIS AND TREATMENT

Background

It is well known that access to, and the quality of, health care is not equal for all Americans. Problems are particularly acute in rural areas and in densely-populated urban areas--in these situations, geography and/or social conditions coupled with a maldistribution of physicians mitigate against adequate health care delivery using traditional methods. One newly-emerging approach to alleviate these problems is that of remote diagnosis and treatment or, alternatively, remote health care.

Remote health care involves diagnosis and therapy with the physician physically remote from the patient. The physician obtains patient information and directs treatment using communication channels audio, video or both. This is usually augmented by observations and actions of a lesser-trained individual (e.g. nurse clinician, physician assistant) at the patient's side.

Remote health care is practiced at present only in very limited fashion at a few experimental sites across the country. Interest in it has been high, particularly in HEW's National Center for Health Services Research and Development. It utilizes much technology. Instruments to collect patient data, means to remotely control diagnostic and therapeutic devices, and the communications links themselves all are required in the ultimate remote health care system.

NASA is in a strong position to assist in the development of remote diagnosis and treatment. It has a significant technological base in biomedical instrumentation, and its developments in physiological transducers and non-invasive measurement devices are at the forefront of the state-of-the-art. Its audio and video communications devices, its expertise in the remote control of delicate processes and its experiences in the remote medical monitoring and treatment of astronauts are directly applicable to civilian remote health care. These factors led the Committee to originally select remote diagnosis and treatment as its third major area of study.

Ad Hoc Group on Remote Diagnosis and Treatment

The Committee initiated work in July, 1970, immediately upon the execution of the NASA/NAE contract. As with the other two major areas of interest (pulmonary and cardiovascular care), an Ad Hoc Group on Remote Diagnosis and Treatment was formed. The Group was composed of members of the CIEBM Subcommittee on Technology and Systems Transfer, physicians from three sites experimenting with innovative remote health care and a representative from NASA's Ames Research Center.*

The Ad Hoc Group transmitted preliminary findings and recommendations to the Subcommittee and the CIEBM. However, as discussed on page 36, the Committee work in remote health care was rather abruptly terminated at the request of NASA in the spring of 1972 and the Ad Hoc Group study was not completed. A short summary of the Group's preliminary findings is provided, however, in Appendix C.

It was the Ad Hoc Group's preliminary opinion that excluding the administrative and political difficulties associated with the establishment of a system for providing remote health care, the primary problems are not in the area of communications. Available technology will, in all likelihood, more than satisfy the medical requirements. However, these requirements are, for the most part, not well defined. The utilization of technical capability within NASA to help establish and satisfy these practical requirements for remote diagnosis and treatment represents a large potential for the application of NASA technology to the problems of health care. The Ad Hoc Group thus made the following recommendations

1. That NASA provide qualified personnel to work with the medical community in carrying out parametric studies and demonstration projects in the area of remote diagnosis and treatment.

* The membership of the Ad Hoc Group is listed in Appendix A.

2. That NASA undertake carefully controlled, goal-oriented experiments to determine the effectiveness of various modes of communications in the delivery of health care to remote locations.
3. That technically competent personnel within NASA be encouraged to interact extensively with bio-medical researchers who have demonstrated an interest in actively applying technology to biomedical problems.

Subsequent Committee Activities in Remote Health Care

Having obtained the preliminary findings of the Ad Hoc Group, the CIEBM Subcommittee on Technology and Systems Transfer devoted considerable attention to remote diagnosis and treatment between April, 1971, and March, 1972. During that period, at the request of NASA, the Academy negotiated a significant cost and contract extension. Effective October 1, 1971, the contract called for a primary and extensive effort in remote health care to build upon the data collected and to initiate specific transfer projects in remote diagnosis and treatment. Significant in the light of future development was the urging of the NASA that the Academy assist in developing mutual, collaborative projects between NASA and mission-oriented health agencies (e.g. Health Services and Mental Health Administration).

The Committee also felt strongly that such collaboration is essential to promulgate effective technology transfer. Thus, in its proposal to NASA's Office of Technology Utilization for this funded continuation, the Academy offered to assist in the design, implementation, and evaluation of remote care projects to be conducted jointly by NASA, health agencies, and medical test sites. The Academy, through the CIEBM Subcommittee on Technology and Systems Transfer, offered to act as advisors to such projects through the establishment of groups consisting of experts in medicine, communications, instrumentation, and transportation. The proposal stated that the Subcommittee would work in conjunction with the newly-formed Institute of Medicine and National Research Council's Committee on Emergency Medical Services to effect this advisory role.

In pursuit of this task, the Subcommittee initiated extensive discussions with representatives of mission-oriented health agencies, conducted further reviews of the literature, and held several workshops on the topic.

Workshops. An Engineering Foundation Research Conference was held in New Hampshire during three days in August, 1971. Co-chaired by the chief staff officer of the CIEBM and the biomedical officer of the NASA Technology Utilization Office, the program was directed to the use of biotelemetry in providing emergency care, intensive (in-hospital) care, and remote diagnosis and treatment. Leading workers from across the country were invited to present and discuss case histories in each category of telemetry application and to discuss mutual problems. A federal agency resources panel responded to these articulated problems in a final round-table session. The meeting was summarized in the open literature.⁴

A second major workshop, which was designed to elicit problem statements from those who deliver remote health care, was held in conjunction with the Academy's Autumn, 1971, Meeting on the Application of Technology to Improve Productivity in the Service Sector of the National Economy. Dr. George Low of NASA chaired the two-day symposium, Dr. Charles Flagle of the CIEBM chaired the workshop on health services. Two directors, heads of an urban and a rural health center, described their systems and problems which they have in reaching remote populations. Federal policy makers as well as other workers in the field amplified upon the problem themes which emerged. Engineers, many of whom represented NASA, responded to these problems with narrow as well as very broad "solutions." Besides filing a report,⁵ the Academy hopes to engender real projects which will attack the problems of productivity identified in health services and the two other areas that were addressed. The work of designing the health project candidate was performed

⁴ "Where Would You Like to Have Your Heart Attack?" IEEE Spectrum 8, pp. 44-50 (October, 1971).

⁵ Application of Technology to Improve Productivity in the Service Sector of the National Economy. National Academy of Engineering, Washington, D. C. (1973).

jointly by a representative of NASA and a medical officer of the Tennessee Valley Authority. The Academy's role in this project was to:

1. Build into the protocol meaningful measures of productivity so as to yield an appropriate evaluation scheme for technology in remote health care,
2. Review the overall proposal and, upon endorsement by the required Academy groups, bring it to the attention of HEW and others which might assume it as a new project.

On October 8, 1971, in Washington, the Subcommittee sponsored an Interagency Workshop on Remote Health Care Systems. Attendance was limited to policy makers from federal agencies having a heavy commitment to health services. The group met to discuss federal priorities in remote health services and how NASA's experts might contribute in the solution of related technological problems. Communications and transportation technology were chief among topics discussed. Plans were revealed within the Health Care Technology Division of HEW's National Center for Health Services Research and Development to deploy and experiment with several video systems in a wide range of medical settings. The revelation of these plans was to be instrumental in future Committee efforts (see page 35).

Attendance at HEW's January, 1972, Conference on Technology and Health Care Systems in the 1980's helped to confirm priorities already visible within the Department's programs.⁶

Meetings. In addition to the above described sources, numerous meetings were held between Academy staff

⁶ Technology and Health Care Systems in the 1980's, Proceedings of a Conference. Collins, Morris F., Ed. U. S. Dept. of Health, Education, and Welfare, Washington, D. C., DHEW Pub. (HSM) 73-3016. January 19-21, 1972.

and Subcommittee and HEW policy-makers to better understand the priorities of the latter group. Drs. Brown and Rockoff of the Health Services and Mental Health Administration addressed the Subcommittee meeting on October 19, 1971, and Dr. Brown spoke again in November to a meeting of the CIEBM Executive Group.

Other agency representatives have been interviewed. Sessions conducted with Veterans Administration officials subsequent to the October 8, 1971, Workshop revealed that the VA presently operates over fifty closed-circuit television systems, some of which link VA hospitals to major civilian medical centers, miles away. This experience should be exposed for the benefit of HEW project planners as well as NASA's engineers who will be engaged in this field. A Department of Defense official informed the Subcommittee staff that the Navy will probably experiment with video communications in remote diagnosis and treatment beginning within two years. At the Office of Economic Opportunity (OEO) an oral briefing summarized current problems in the operation of neighborhood health clinics. The multiple problems which plague the attempt to deliver quality health care to large numbers of the urban poor make it unlikely, in the view of the OEO, that groups such as NASA could provide any major contributions for the time being. Other answers must precede those which technology can yield.

Members of the Subcommittee and staff have discussed health priorities at the state level with representatives of the Wisconsin Governor's Health Planning and Policy Task Forces and, briefly, with a representative of the Nevada Governor's Office.

Besides determining federal and state agency priorities, the Subcommittee sought other means to enhance its understanding of the major problems which exist in the delivery of remote health services. Statements were solicited from individual discussions with workers such as those involved in Missouri's Automated Physicians Assistant Program and the telemedicine video system centered at the Massachusetts General Hospital. Meetings also were held with representatives of the White House Office of Science and Technology and the National Library of Medicine. These sessions determined that both agencies were willing to participate in an interagency

effort to ascertain the role of technology appropriate in remote health care delivery.

Finally, a small but direct experience with examining a patient at a distance was begun in May, 1971, by Subcommittee members at the Telemedicine link between Logan Airport and the Massachusetts General Hospital (MGH) in Boston. It was subsequently continued at the VA Bedford Hospital-MGH Teleconsultation link.

Pursuit of an Interagency Development Project

As noted above, the Committee had accepted with enthusiasm the challenge of assisting in the establishment of a joint collaborative project between NASA and a mission-oriented health agency to develop and deploy useful remote health care technology. In the fall of 1971, the National Center for Health Services Research and Development (NCHSRD) of the Health Services and Mental Health Administration (HSMHA) was preparing to fund seven experiments in the use of video (closed-circuit TV and picturephones) for remote health care. At the same time, Johnson Space Center (JSC) staff members were preparing a proposal for a parametric study of the effects of resolution, refresh rate and color in remote diagnosis and treatment using video channels. The latter was to be funded by NASA's Office of Technology Utilization.

Thus the means of developing a model collaborative program between NASA and HSMHA was right at hand. The Subcommittee and CIEBM staff seized the opportunity, made several preliminary recommendations to each group, and attempted to establish cooperative arrangements by overseeing planning meetings between JSC and NCHSRD personnel. Many such meetings and communications transpired during late 1971 and the first two months of 1972. In addition to suggesting technical objectives, the Committee prepared a preliminary joint management outline (Appendix D) at the request of NASA to serve as a basis for a definitive negotiation of an interagency agreement.

Nevertheless, the joint project was not to be. The JSC approach was to investigate video parameters in a carefully controlled laboratory-like setting. NCHSRD felt that preceding such definitive investigations, experience should be gained

in adding video communications to existing and on-going health care delivery situations. Its program was designed to conduct initial experiments on the effects of video parameters in real health care settings and desired JSC assistance in providing the technology and engineering expertise to do so. However, it became impossible to convince JSC personnel to alter their protocol to meet the health care delivery objectives being pursued by NCHSRD while NCHSRD personnel expressed grave doubt about the value and validity of the JSC approach. Each project eventually was undertaken separately, with liaison for coordination established. The JSC project, incidentally, encountered early problems much as NCHSRD personnel predicted. Invited to attend NCHSRD project reviews of its demonstration projects, JSC received sound advice from the NCHSRD contractors which caused a major redirection of the JSC study.

Termination of the Committee Remote Health Care Study

In the spring of 1972, the Committee was invited to discuss its various efforts with the Office of Life Sciences (OLS) within NASA's Office of Manned Space Flight. This office had recently been given expanded responsibility for NASA life sciences programs and Dr. Charles Berry was its newly-appointed Director. At a meeting for the purpose on March 8, 1972, the Committee was directed to immediately terminate all efforts in remote health care. OLS was assuming the agency lead in remote health care, relieving the Office of Technology Utilization of the function. It did not desire further Academy assistance at the time.

Thus Academy efforts in remote diagnosis and treatment came to an end without benefit of closure of the many avenues that were open and under investigation.

URINE BACTERIA DETECTOR

URINE BACTERIA DETECTOR

Background

Early in its study of NASA technology potential for health care, the Subcommittee was made aware of a bio-assay technique that could be valuable in the rapid detection of bacteria. The system uses the luciferase (firefly) reaction with ATP, a substance present in all bacteria. The presence of bacteria is measured by detecting flashes of light given off in the ATP-luciferase reaction with a photomultiplier device. The value of the system over current methods is primarily its speed, present culture techniques demand 24 - 48 hours, whereas the luciferase system can effectively measure the increase in the quantity of bacteria (i. e., growth rate) within about three hours. It would be particularly useful in the selection of an antibiotic to treat a given infection as it can be used to quickly determine the susceptibility or resistance of a particular bacterium strain to a selected antibiotic.

Personnel at the Goddard Space Flight Center had been working with this technique for some time, and thus it appeared to the Subcommittee that this technique would be potentially useful in measuring the sensitivity to antibiotics of bacteria contained, for example, in urine. The Goddard personnel were responsive to the Subcommittee idea. Under arrangements made by and overseen by the Subcommittee, a pilot experiment was conducted at the New England Medical Center Hospital (NEMCH) where the luciferase method was tested in comparison to standard bacterial determinations using cultures. This occurred in October, 1971. The correlations between the two methods were good enough to suggest that further development of the luciferase method was worth pursuing.

Establishment of a Long-Term Joint Transfer Project

A number of theoretical and practical questions require answers, and a thorough clinical evaluation must be performed before the technique can be unequivocally recommended. A NASA-Goddard/NEMCH team, together with the Subcommittee, formulated a rigorous three-year protocol which would address these issues in a collaboration between NEMCH

and NASA-Goddard personnel. The proposal, including the protocol and the funds required, was submitted to NASA Headquarters and NASA-Goddard management in November, 1971.

It was subsequently revised and prepared in final form in April, 1972 (Appendix E). The proposal called for a total expenditure of \$212,200 over three years; \$112,200 to support staff and expenses at NEMCH and the remainder to cover direct expenses at Goddard. NASA staff salaries of Goddard personnel were to be contributed by the space agency in addition.

A long negotiation process ensued involving NEMCH, the NASA-Goddard staff, NASA-Goddard management and NASA Headquarters. A change in management personnel at NASA-Goddard coupled with a reluctance of NASA management to commit the time of the Goddard staff to the project contributed to considerable delay. [≈] NASA's Office of Technology Utilization agreed in October, 1972, to fund the three-year project in the amount of \$172,200, and NASA-Goddard agreed to commit the necessary Goddard investigators to the project.

There followed a lengthy legal negotiation of a joint agreement between NEMCH and NASA-Goddard. This was consummated in January, 1973, thus bringing to fruition a project whose value had been recognized in October, 1971. Some fifteen months of non-technical administrative activity was required to move from recognition of a transfer potential to initiating the next step in the transfer process.

Present Status

With the NEMCH-NASA agreement now in being and operative, the role of the Academy is completed. The transfer

[≈] This negotiation took place during a period when the number of personnel allocated to the Goddard Space Flight Center was being reduced by NASA Headquarters. Goddard management was understandably reluctant to further reduce the staff assigned to its primary mission programs by assigning personnel to this technology utilization project.

potential has been identified, the research and development requirements are specified, the necessary federal and private institutional arrangements have been made, and the transfer process has been launched. Of all projects initiated by the Committee, the urine bacteria detection system may thus serve as the best illustration of three fundamental contentions.

- (1) Significant transfers in health care cannot be expected to be accomplished in less than about five years, from identification of potential to deployment in the health care delivery system.
- (2) The accomplishment of significant transfers in health care delivery most often will require the expenditure of considerable resources.
- (3) Interested and competent personnel for the agencies representing the technological source and the ultimate user must be identified and provided a sound, joint working arrangement if they are to effectively collaborate on a significant technology transfer program.

Progress since January, 1973, has been satisfactory. Appendix F provides a summary of recent results of initial comparisons of two luciferase bacterial assay procedures with microscopic and plate count determinations.

REPRODUCIBILITY OF THE
ORIGINAL PAGE IS POOR

EMERGENCY MEDICAL SERVICES

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EMERGENCY MEDICAL SERVICES

Background

As explained on page 36, the Committee terminated a major activity -- a study of technology application to remote diagnosis and treatment -- at the end of March, 1972. Subsequently, in May, 1972, NASA asked the Committee to identify technological requirements in the field of Emergency Medical Services (EMS), and to suggest technological needs that could benefit from an application of NASA technology or expertise. Work was immediately begun under the overview of the CIEBM Subcommittee on Technology and Systems Transfer. CIEBM and Subcommittee member Dr. Elsworth Buskirk was requested to assume leadership of this part of the Subcommittee efforts.

After an initial examination of the EMS field, the Subcommittee realized that to explore the entire field would be impossible. With NASA approval, the study was limited to primarily considering communications needs in EMS systems. The communications area was chosen because. (1) it comprises a major involvement of technology in EMS, and (2) should unfulfilled needs be identified, the probability would be high that NASA's broad communications expertise would be applicable to solutions.

The Subcommittee conducted its study in three ways:

- (1) An intensive study of the literature was performed.
- (2) In conjunction with the Subcommittee on Emergency Medical Communications of the Committee on Emergency Medical Services, NRC, a comprehensive report detailing the functions to be performed by an EMS communications system and alternative ways to meet them was prepared (Supplement III).
- (3) Site visits were made to selected locations in the nation that were known to be leaders in the development of EMS systems. These sites included four of the five originally chosen by the Health Services

and Mental Health Administration (HSMHA) as model demonstration programs. Discussions were held with personnel at all levels of the systems visited, from top administrators and physicians to ambulance attendants and emergency room nurses. At several sites, Subcommittee representatives observed systems in action by riding as observers on ambulances for many hours at a time. Locations visited were.

1. State of Illinois Trauma System (Cook County Hospital)*
2. Houston, Texas
3. Ohio Valley Health Services Foundation, Athens, Ohio*
4. San Diego County, California*
5. City of Los Angeles and the University of Southern California Department of Emergency Medicine
6. City of Baltimore and the University of Maryland Center for the Study of Trauma
7. District of Columbia
8. Nassau County, Long Island
9. Virginia Beach Emergency Coronary Care Program, Virginia Beach, Virginia
10. Jacksonville, Florida*

* HSMHA demonstration sites.

11. Miami, Florida⁺

12. Detroit, Michigan⁺

Summary of Findings

The Subcommittee found that technology is not a limiting factor in the provision of quality emergency medical services. Organizing the many independent entities (political bodies, hospitals, medical societies, ambulance services) into an integrated, collaborative regional EMS system presents the greatest challenge. Almost without exception, the communications hardware required is commercially available, off-the-shelf.

Many of the communities currently embarking on the development of area-wide, improved EMS systems do not have communications systems expertise easily available to enable them to effectively design, procure, install, test and operate the available hardware. Many have had to rely on the recommendations and designs offered by suppliers of hardware, accepting the obvious bias that such a source of advice contains.

Recommendation

NASA could provide a service to EMS systems implementers by providing consultation on communications systems design, development of procurement specifications, and methods of certifying performance of installed equipment.

Sites visited that indicated a desire for this type of consultation included Houston, Texas; San Diego, California; and the State of Maryland. Representatives of local field centers (Johnson Space Center for Houston; Goddard Space Flight Center and NASA Headquarters Office of Applications for Baltimore, Jet Propulsion Laboratory for San Diego) were invited to accompany the Subcommittee and staff on site visits to initiate direct

⁺ Visits to these sites were funded by agencies other than NASA.

dialogue between EMS providers and sources of local EMS assistance.

Miscellaneous Technological Improvements

While technology did not appear to be a major constraint in providing adequate emergency medical care, a number of persons interviewed on the site visits suggested technological improvements that they thought might be of some value. It was the estimate of the Committee that these developments would not result in significant changes in the quality of EMS, though a thorough investigation of how universal these needs might be has not been made. The suggestions are listed below, the site originating each suggestion is identified.

1. Integrated, portable EMS cardiac equipment.
This unit would contain in one suitcase-type carrier an ECG monitor, telemetry transmitter, two-way voice transceiver, defibrillator, oxygen (resuscitator) supply, suction device, blood pressure measurement device, IV kit and drug administering equipment.
(Houston, Texas)
- Note See Appendix G for a further discussion of this equipment.
2. A simply-attached external VHF antenna to permit a portable transceiver to be used in a helicopter not permanently outfitted with EMS communications radios. (Illinois)
3. Miniaturized, high-power density battery power supplies for portable suction, resuscitator, telemetry, radio, defibrillator equipment, etc.
(Virginia Beach)
4. An easily controllable intravenous administration set. (Cook County, Illinois, Trauma Center)
5. A blood pressure measurement device suitable for use in an ambulance whose high ambient noise levels makes the use of a standard sphygmomanometer difficult. (Houston, Texas)

6. A cheap UHF multiplexed ECG telemetry-voice portable transceiver. (Houston, Texas; Los Angeles, California)

Note: At least one manufacturing company, Pioneer Systems, Inc., provides such a unit commercially.

7. A strong portable suction unit, lightweight and small, with at least a 1/2-hour capacity. (Los Angeles, California)

APPENDIXES

APPENDIX A

SUBCOMMITTEE ON TECHNOLOGY AND SYSTEMS TRANSFER

AD HOC GROUP ON PULMONARY CARE

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APPENDIX B

November 28, 1972

STATUS REPORT OF THE MASS SPECTROMETER - RESPIRATORY FLOWMETER PROJECT OF THE AD HOC GROUP ON PULMONARY CARE,

Prepared by: E. R. Buskirk, P. A. Drinker, C. W. Garrett

Following the publication and distribution of the Pulmonary Care Report, in the summer of 1971, with NASA's support the Subcommittee undertook to implement the major recommendation of that report: namely the design, assembly, installation and testing of a mass spectrometer - respiratory flowmeter system for use in intensive respiratory care. At the time the report was issued it seemed clear that there was no respiratory flowmeter available which met the necessary criteria of accuracy, stability, sensitivity, simplicity, and ruggedness which would be necessary for routine intensive care use. Therefore, as a specific project, NASA undertook the support of a new flowmeter developed by Bowles Fluidics under a previous NASA contract. This project is now underway and it is expected that prototype models will be available for testing during the coming year.

Regarding the mass spectrometer part of the system, progress has not been as clear cut, and the Subcommittee directed the writers to reassess the situation.

Information gained during the past year shows that during this intervening period several industrial groups have moved ahead with their own independently supported development projects which, in fact, match closely many of the criteria outlined in the Subcommittee report. In particular, Perkin-Elmer, the firm which NASA had supported in a preliminary development of a mass spectrometer for use in spacecraft, has introduced a medical gas analyzer (magnetic sector mass spectrometer) designated MGA-1100. The conversion from the spacecraft prototype to the clinical analyzer was carried out by Perkin-Elmer without NASA support. In addition to the Perkin-Elmer unit, several others are available at the present time for

clinical use. These included two mass spectrometers built by Vacuumetrics, Inc., a quadrupole analyzer made by Automated Medical Systems, Inc., the magnetic sector device (Medspect) made by S.R.I., a quadrupole system developed by a British firm (Centronic) and several others such as the older Bendix time-of-flight spectrometer and the Varian MAT-3.

During 1971-1972, efforts were made by inviting a proposal from the Respiratory Care Group of the Massachusetts General Hospital to redirect the emphasis of the study from technical development of the mass spectrometer systems to their implementation and testing in a clinical setting. This type of project involved support for professional and paramedical workers in respiratory care units. It became evident that NASA was not in a position to support this type of project, and collaborative efforts with other federal agencies also stalled.

During this time, information was obtained from all known manufacturers of medical gas analyzer systems (Attachment 1) with particular emphasis being placed on mass spectrometers. Information as to their range of applications, state of development, availability, and other pertinent features were compiled.

With this information in hand, it seemed advisable to reassess the entire project, and in particular to make a site visit to one or more of the groups who were reported to be well-advanced in the application of a mass spectrometer-flowmeter system. The groups selected were: (1), that headed by Arnold S. Leonard in the Department of Surgery, University of Minnesota, Minneapolis, who is working in close collaboration with Automated Medical Systems, Inc., also of Minneapolis, and (2), the University of Maryland's Center for the Study of Trauma under the direction of R. Adams Cowley. On September 25 and 26, 1972, Messrs. Buskirk, Drinker and Garrett visited the Minneapolis group, reviewed their progress in implementing a clinical monitoring system for respiratory care, and were able to develop updated conclusions and recommendations. On November 9, 1972 Messrs. Buskirk and Garrett visited the University of Maryland site in Baltimore.

University of Minnesota

The Minneapolis workers have had several years experience with a computer system based on a Honeywell 516 computer; software and terminals are provided by Automated Medical Systems (AMS). There are 16 portable terminals which may be tied in to the computer from the operating room, recovery room, intensive care unit, pediatric intensive care unit, catheterization lab, coronary care unit, and the pulmonary function laboratory.

We had several reactions to the computer system as we saw it in use. First, the terminal designed by AMS looks to be one of the most functional of any seen thus far. For example, the function keyboard clearly spells out such instructions as patient review, lab reports, etc. It appears to be a powerful educational tool, and certainly the Minnesota group is highly enthusiastic about it. On a quick inspection, however, it was difficult to see exactly how the care of the patient depended on the computer, it seems that its primary function may well be as a ward secretary. To fully evaluate the question of its impact on medical care would take a longer study than we could carry out, but it appears that nurses, technicians and doctors all can use it with ease. Among other things, all data entries are coded in terms of time, so that retrieval is easy, and different aspects of the patient's course can be reviewed. The computer has storage capacity for up to four days, after which time it must be cleared, with the stored material put out on a line printer or some type of tape storage.

Given their background of experience with the computer and overall monitoring, it was clear to us that the Minnesota group views the mass spectrometer-flowmeter package as being valuable in that it can relate to the bigger system; it simply becomes an additional source of input data, and thus they are working beyond the simple spectrometer-flowmeter-minicomputer package that had been outlined in the Pulmonary Care Report.

In setting up arrangements for this visit, the writers had been assured that they would see the mass spectrometer-flowmeter package in actual use in the care of patients. This proved not to be the case. Rather, the mass spectrometer was wheeled into the pediatric intensive care unit and attached to an infant for our benefit. It had not be calibrated, nor was the flowmeter operating. By prior telephone conversations the impression had been given that this was a working system in

actual use on which the doctors depended for the care of their patients. However, they seemed to be managing the babies adequately in the intensive care unit without the use of the mass spectrometer-flowmeter. We asked what was impeding its actual routine application: was it cumbersome in its use; was it unnecessary from a medical standpoint? These are central questions that must be resolved in order to fully determine the need for a mass spectrometer in the respiratory care setting.

In attempting to probe these points with the University of Minnesota workers, several comments are relevant. First, the mass spectrometer-flowmeter-computer package has a makeshift interface with the main computer which requires considerable effort on the part of the user and takes full-time babysitting. In other words, the technology is not complete insofar as integrating and interfacing the package is concerned. A second possibility is that because the instrument is still difficult to use, there is not enough experience with it to know just how relevant the data will be to the care of the patient.

Regarding the use of the computer system by the University of Minnesota as a possible model to be followed in other medical centers, their interest and concern with the cost of the operation was extremely interesting. Based on the 16 terminals, with a working figure of 750 hours a month, there are approximately 11,000 terminal hours available on the system each month. To support the cost of programmers, technicians, and some physician time, as well as supplies, they are currently charging each patient \$2.00 per hour on the computer monitoring system. Total billed income currently averages \$9,000-\$10,000 per month. The monitoring covers the usual vital signs plus laboratory and other data entered manually. Before establishing this as a regular billing procedure, Dr. Leonard discussed the approach with various representatives of Blue Cross-Blue Shield who enthusiastically supported the idea once he had laid out the economics with them. It does seem clear that while in their case they have the machine through contract from Honeywell and will obtain it free of charge at the end of the contract, the charge would not need to be substantially increased to allow for equipment amortization on a completely rational basis.

In the course of discussions with Drs. Leonard and Warren Warwick (both with the University of Minnesota) and Dr. M. Mosharrafa of Automated Medical Systems, it appeared that there are several mass spectrometer systems now worth testing in a clinical setting (as opposed to the various research applications in respiratory physiology). These include the Perkin-Elmer unit, the AMS spectrometer, and the Centronic spectrometer, although the latter in its current configuration is still a bit complex for easy clinical use.

Regarding the flowmeter situation, although we saw and heard evidence about other systems, it is still not clear that anyone has produced a flowmeter which is better or more reliable than the Fleisch pneumotachograph which, as indicated in the Pulmonary Care Report, is not good enough. The writers were not able to see the Thermo-systems hot film flowmeter used by AMS in operation. They were assured that although not optimum (it measures flows in one direction only), it was reliable and could be used. The visitors remain to be convinced. On the second day of the visit, a representative from Beckman joined the discussions and had with him one of their inert gas dilution flowmeters which could be used with any mass spectrometer system (assuming it had an extra two channels for xenon and krypton). In principle, the Beckman flowmeter offers the extremely attractive feature that not only are fewer instruments required (both flow and gases are measured with the same instrument), but the time delay problems of a separate flowmeter are eliminated because the inert gas traces are in phase with the respiratory gases. The current design, however, appears to be totally unsuitable for clinical respiratory monitoring, and it would need modification even for exercise physiology studies. In its present form it depends on a fine bore honeycomb structure which will certainly plug or foul with moisture, sputum, etc. even if the unit were heated, which it cannot be with its present construction (plastic).

The Beckman representative indicated that the development of this flowmeter was currently being supported out of Houston by NASA and that this development support would continue through its application and installation on helmet-mask assemblies for the astronauts. For it to be applied to the clinical monitoring situation it would have to

be extensively redesigned and tested. It certainly appeared to the writers that while the Beckman flowmeter may offer interesting possibilities and be worth pursuing, the Bowles project is completely justified and in fact necessary.

In the Pulmonary Care Report it was stated that magnetic sector mass spectrometers appeared to be promising in terms of both stability and accuracy. Technologic advances during the past year have overcome many of the problems of drift and lack of precision which had plagued the quadrupole systems, and it was the consensus of those present at the meeting (Attachment 2) that the quadrupole systems are now at least as good in performance, they offer more versatility and can be made smaller in size. Dr. Mosharrafa pointed out one serious technological need which is common to all quadrupole devices. the development of a stable, high gain (amplification factor in the range of 10^8) electron multiplier. (Because the magnetic sector devices operate with fixed collectors, amplification can be carried out with a much lower band width, and therefore presents less of a problem.) All agreed that this may be a specific area to which NASA can contribute rapidly and effectively, and it was agreed that this question should be raised by the Subcommittee.

When pressed to answer the question "what are your specific needs which must be met if you are to test and prove the worth of a mass spectrometer-respiratory flowmeter-computer system for use in respiratory care monitoring?" the University of Minnesota and AMS representatives presented reasonably concise answers which may be summarized as follows:

1. Although the monitoring computer is functioning, and the mass spectrometer itself is available, the integration of the two into a usable system is not complete. For completion, more work is needed on software development and specific hardware for interfacing the two packages. Some progress could be made with existing flowmeters; this progress will be readily transferable to a new flowmeter when it becomes available. Further technical needs would include the development and implementation of specific automated functions such as calibration cycles and additional components for AD/DA conversion. Should adequate membrane catheters become available, mass spectrometry blood gas measures will be useful and may permit future development of computer-operated respirators. We learned from Dr. Warwick that a British group has developed such a catheter and has reported promising results.

2. In the area of future hardware developments, AMS pointed out that mass spectrometers are basically digital instruments (they count electrons) and thus should be interfaced directly with the digital computer rather than going through the DAD conversion that all medical (but not industrial) mass spectrometers now use. Dr. Mosharrafa urged provision for future development, based on this principle, of a new mass spectrometer-microcomputer package. The feeling of the writers is that this should follow phase 1--i. e. the initial concept testing in the clinical environment.'

Some discussion was directed at the question as to whether or not we should now be concerned with testing and evaluation of competitive systems rather than simply selecting one which appears to be suitable to answer the questions we pose. The University of Minnesota AMS group is most familiar with the AMS equipment; however, Dr. Leonard stated that should competitive testing be deemed useful, it could be carried out simultaneously with the clinical stages because they already have considerable familiarity with the various systems. AMS is currently working under subcontract to the University (under HSMHA support) and there would be no conflict of interest involved.

In response to questions as to the level of support needed to carry out basic clinical testing of the mass spectrometer-flowmeter-computer package, the University of Minnesota group indicated that the total cost for the first year would be of the order of \$92,000, including indirect costs. Dr. Leonard indicated that if invited he would be happy to submit a proposal, with detailed budget and work plan, and that he would indicate those areas in which support from other sources could be sought if necessary.

University of Maryland

Scientific Research Instruments (SRI) magnetic sector mass spectrometer has been placed on line via a manifold system with each of the twelve beds in the Emergency Care Section, on the fourth floor of the Trauma Center. An additional line will soon be run to the hyperbaric chamber situated in a room several floors below the Emergency Care Section. These 1/8 inch copper inlet lines can, in the opinion of the staff, be extended from the present 50 foot length to about 100 feet without difficulty.

A programmable Wang desk calculator serves as a systems controller and data reduction device. It controls the manifold valves and the spectrometer. Printed output is obtained on a selectric typewriter, driven by the Wang, at the nurse's station. Automatic calibration of the system (one manifold inlet line comes from a calibration gas source) is controlled by the Wang which also corrects for the inlet transit times separately for each of the twelve lines.

Although a modified Fleish pneumotachograph is currently being used to monitor airway flow, experiments are being conducted with a Statham Ultrasonic spirotach (Model SP 1009). The opinion was expressed that this Statham flowmeter offered the excellent possibility of eliminating many of the problems experienced with the Fleisch; e.g., the Statham unit does not have to be heated and a temperature correction does not have to be made. Gas viscosity, water vapor, and velocity corrections still must be made but these can be handled by the attached programmed Wang desk calculator. Statham has provided two flowmeters to be used in this development; the Center staff has considerably modified the electronics of the unit and is developing software for the Wang calculator to perform the necessary corrections.

At the moment the greatest emphasis in routine patient monitoring is being placed on alveolar $p\text{CO}_2$ measurements although attention is also paid to airway O_2 concentration and to airway pressure. The eventual system as they foresee it would involve:

- (1) Patient with tracheostomy or endotracheal tube on volume controlled ventilator
- (2) Flowmeter (modified Statham)
- (3) Sampling line via manifold system
- (4) SRI mass spectrometer
- (5) Wang 730 programmable calculator
- (6) Appropriate software packages

Their reasons for wanting a mass spectrometer in their overall monitoring system were to:

- (1) Utilize a noninvasive system for monitoring
- (2) Reduce number of samples for blood gases
- (3) Provide more quantitative appraisal than clinicians' impressions.

The mass spectrometer was regarded as the only analytical instrument available that was sufficiently versatile, rapid, accurate, and stable to provide the necessary respiratory information. Of particular interest was their view that the need for blood gas measurements can be reduced by a factor of four or more (e.g., from once every hour to once every 4-6 hours) by having accurate, breath-by-breath respiratory data continually available.

When asked if the Emergency Care Section staff would miss the system were it shut down, Dr. Turney replied that the staff (nurses, attending physicians) now routinely relies on the data as a monitor of patient condition and that the system would be missed. He noted that initially, there was an educational problem with the Trauma Center staff but that once the data are understood they are used in a competent way.

The estimates on cost were \$5,000/bed to install the twelve-bed system. Payment can be met by patient charges.

Money is required for further developmental work to obtain an on-line functional system that includes the Statham flowmeter. In our view the team at the Center must be included in the forefront of those developing and using (in routine patient care) the pulmonary measurement systems recommended by our Ad Hoc Group. They are in a position and would be competent to perform the clinical development and evaluation of the proposed spectrometer-flowmeter-computer system.

Attachment 2 (Appendix B)

Sample Letter and List of Addressees Used in State-of-the-Art
Determinations

May 22, 1972

Gentlemen:

Under contract to the National Aeronautics and Space Administration, our Committee in the National Academy of Engineering is performing a study involving instrumentation in intensive pulmonary care for patients with respiratory ailments. We are particularly interested in the use of mass spectrometers for respiratory and/or in vivo blood gas determinations.

I would appreciate it very much if you could forward as soon as possible complete information on your firm's mass spectrometers that are intended for use in the medical environment. We are interested in their design parameters (type, size, resolution, stability, mass range, response time, etc.) and cost. In addition, we would like to know:

1. Clinical locations (a representative list of several, if large) where they are in use for respired air measurements.
2. Identical list for continuous blood gas measurements.
3. Any locations that are using one spectrometer for both respiratory and blood gas measurements together (i. e., with sample input manifolding to permit both determinations in short periods of time).
4. Locations where the spectrometer is tied to other devices (e. g., flowmeters and/or computers) to obtain derived clinical data from the basis spectrometer output.

If your company has other means (not using mass spectrometers) to obtain in vivo blood gas and/or breath-by-breath respiratory gas analyses, we would be interested in similar data.

Page 2
May 22, 1972

Thank you very much for your trouble. I hope to hear from you soon, as we are in immediate need of this information.

Yours very sincerely,

Charles W. Garrett
Executive Secretary

CWG:ms

Copy to Dr. Rutstein
Dr. Buskirk
Dr. Drinker

Addressees

Dr. Peter Fowler
National Research Corporation
Memorial Drive
Cambridge, Massachusetts 02139

Bendix Scientific Instruments
and Equipment Division
1775 Mt. Read Boulevard
Rochester, New York 14603

Scientific Research Instruments Corp.
6707 Whitestone Road
Baltimore, Maryland 21207

Vacumetrics
241 Crescent Street
Waltham, Massachusetts 02154

Perkin-Elmer Medical Instruments
Attn: Mr. Wayne J. Whistler
2855 Metropolitan Place
Pomona, California 91767

General Electric Corporation
Medical Systems
4855 Electric Avenue
Milwaukee, Wisconsin 53201

Varian Associates
611 Hansen Way
Palo Alto, California 94303

JEOL (USA), Inc.
235 Birchwood Avenue
Granford, New Jersey 07016

Process and Instruments Corp.
1943 Broadway
Brooklyn, New York 11207

Hewlett-Packard Medical Electronics Div.
175 Wyman Street
Waltham, Massachusetts 02154

Nuclide Corporation
642 East College Avenue
State College, Pennsylvania 16801

Finnigan Corporation
595 North Pastoria Avenue
Sunnyvale, California 94086

Edwards High Vacuum, Inc.
3279 Grand Island Boulevard
Grand Island, New York 14072

du Pont Instrument Products Division
Wilmington, Delaware 19898

Aero Vac Corporation
65 Arch Street
Green Island, New York 12183

Lawrence Electronics Company
Medical Division
14636 Ambaum Boulevard, S.W.
Seattle, Washington 98166

Physio-Control Corporation
2607 Second Avenue
Seattle, Washington 98121

Automated Medical Systems, Inc.
3050 Metro Drive
Suite 115
Minneapolis, Minnesota 55420

Universal Hospital Services, Inc.
(Distributor for Centronic, Ltd.)
2438 27th Avenue, South
Minneapolis, Minn. 55406

Attachment 2 (Appendix E)

Persons attending meetings at the University of Minnesota Medical Center, Minneapolis, Minnesota, September 25 and 26, 1972.

For the National Academy of Engineering, Subcommittee on Technology and Systems Transfer:

E. R. Buskirk
P. A. Drinker
C. W. Garrett

For the University of Minnesota:

George S. Bergh, Jr., M.D.
Carl E. Hunt, M.D.
Arnold S. Leonard, M.D.
Sandy Matalan (Medical Student)
William M. Stauffer, M.D.
Warren Warwick, M.D.

For Automated Medical Systems Company:

William Boam
John H. Erickson
Mostafa Mosharrafa, Ph.D.

For Universal Hospital Services:

Richard A. Braatz
Edward H. Fish

For Beckman Instruments:

John M. Walsh

Persons attending the University of Maryland Center for the Study of Trauma, Baltimore, Maryland, November 9, 1972.

For the National Academy of Engineering, Subcommittee on Technology and Systems Transfer:

E. R. Buskirk
C. W. Garrett

For the University of Maryland:

R. Adams Cowley, M.D.	Director of the Center
Stephen Z. Turney, M.D.	Director of Emergency Care Section
David Wilson	Mathematical Statistician
Walter Blumenfeld	Biomedical Engineer

APPENDIX C

PRELIMINARY FINDINGS OF THE AD HOC GROUP ON REMOTE DIAGNOSIS AND TREATMENT

Initially, the Ad Hoc Group explored the medical requirements for the delivery of health care to remote areas without regard to the potential of present or future technology. Agreement was reached on a simplified version of a remote health care delivery framework. This design included teaching hospitals, community hospitals, outlying physicians, remote care stations, patients, and communications and transportation techniques as major elements. Within this framework, the Ad Hoc Group began an analysis of.

1. The functional requirements of remote health stations (i. e., facilities with no physician in attendance).
2. The interaction that would take place between a health station and a physician remotely directing primary medical care at the station.
3. The interaction that would occur between a physician and a remotely-located specialist (e. g., between a general practitioner and a cardiologist.
4. The overall health care requirements that affect remote diagnosis and treatment.

By such techniques as examining the content of the basic general physical examination, the Ad Hoc Group developed a preliminary concept of the medical requirements for remote health care and the availability and potential of technology to satisfy them. Seventeen medical requirements grouped in five categories that were selected are listed below.

A. Communications Requirements

1. Methods for narrow band video communication between a remote station and a central hospital.

2. Methods for broad band, high data rate communication between remote stations, and a central hospital.
3. Methods for broad band audio transmission over existing phone lines. Of primary interest is the transmission of heart and breath sounds from remote stations where video transmission is not practical.
4. Methods of transmitting and displaying color information on black and white video displays.

B. Data Handling and Computation

1. Methods for banking and retrieval and large amounts of medical information at many remote stations.
2. Interactive, flexible and inexpensive computer terminals.
3. A system for updating diagnostic and therapeutic information and making it available to physicians.
4. Standard methods of obtaining and storing medical histories.

C. Physiological Measurements

1. A method of transferring detailed endoscopic video information from a remote location to a central hospital.
2. Methods for measuring the size or volume of internal organs or glands.
3. Standard procedures for monitoring gait and measuring muscle tone and power.

4. Methods for transferring tactile fremitus information from the remote patient to a central hospital.

D. Personnel

1. Method for insuring the confidentiality of the transmitted information.
2. Methods to overcome the human and legal problems concerning the acceptance of technology and the concept of the nurse clinician delivering health care.

E. General

1. The application of image enhancement techniques to the transmission of medical information.
2. Application of the central complex-remote terminal concept to sophisticated and expensive medical equipment in order to provide the benefits of modern medical technology at remote locations.
3. The application of automated trouble-shooting procedures for complex medical equipment.

In order to locate and effectively appraise technology and capability within NASA that might be applied to satisfy them, a clear articulation of the medical requirements is necessary. Unfortunately, only some of those listed above are clearly specified and can be evaluated easily. Many others are generalized and ill-defined; they require further attention by those who can sharpen the statements that describe adequate medical care for "remote" populations.



APPENDIX D

NATIONAL ACADEMY OF ENGINEERING 2101 CONSTITUTION AVENUE, N.W., WASHINGTON, D.C. 20418

Committee on the Interplay
of Engineering with
Biology and Medicine

March 3, 1972

Mr. Jeffrey Hamilton
NASA Headquarters, Code KT
400 Maryland Avenue, S.W.
Washington, D. C. 20546

Dear Jeff:

We have spent some time considering appropriate ways in which a joint NASA - HSMHA project might be administered. Before suggesting a specific approach to the NASA MSC video parameter study proposal, let me reiterate two fundamental reasons why we feel a close and continued collaboration between NASA and the mission-oriented health agency is essential when NASA is participating in a demonstration or development of technology for health care applications.

1. From its inception, any such project must be closely coupled to the existing problems and characteristics of the health care delivery system. The mission-oriented health agency (e. g. HSMHA) is the best federal agent to carry knowledge of the "real world" to the project to be sure that the demonstration's output has relevance to pressing existing problems and can, if successful, be injected into the delivery system. In our view, the internal NASA medical component is not in a position to contribute to a project the broad national comprehension of delivery system characteristics which is available to HSMHA or like offices. .
2. The ultimate objective of any such project must be that beneficial results are transferred to and utilized by the delivery system. This implies that a "transfer agent" which has a direct influence upon the delivery system is required. Clearly, HEW and its offices have greater ability to carry

the results to the delivery system at large and have certain leverage (e.g. funds, ability to promulgate certain rules and regulations, influence on health legislation) not available to NASA to further the transfer process. In our view, HSMHA should be identified as the transfer agent.

It further seems a fact of life that HSMHA would feel much more committed to acting as the transfer agent when it has been involved from the very beginning, is assured through continued participation of the value of the results, and can identify the project as being an integral part of its program as well as that of NASA's. In short, to optimize the probability of a meaningful project producing results which are successfully transferred, a truly joint interagency arrangement with shared management prerogatives and funding is necessary.

Turning to the specifics of the Houston video study, we would suggest a joint project management team composed of HSMHA and NASA staff. However, for each defined function and responsibility, one agency must be assigned the lead responsibility and be given final decision authority. The following table is offered to serve as a starting point in negotiating such an arrangement. It emphasizes HSMHA's role as managers of the clinical setting and NASA's role as suppliers of technology and (most important) the technique of sound systems analysis and management. The table must be considered preliminary, in all likelihood not all functions are specified, and those that are require further refinement and definition.

In conclusion, it should be noted that NASA's prime contribution to this project is systems and communications expertise AND the ability to construct an objective, quantitative systems evaluation scheme. These are what NASA uniquely has to offer HSMHA. In our opinion, NASA should not shy from supplying off-the-shelf, commercially available communications hardware if such is required to accomplish the overall objective of effectively evaluating the role and characteristics of video communications in a clinical setting.

Mr. Jeffrey Hamilton

-3-

March 3, 1972

I hope this satisfies the charge you gave us, and we will be looking forward to your reactions.

Yours very sincerely,

Charles W. Garrett
Executive Secretary

CWG.ms
Enclosure

Copy to Mr. Richards
Dr. Rockoff
Dr. Ayers
Mr. Von Renner

FUNCTION

REPRODUCIBILITY OF THE
ORIGINAL PAGE IS POOR

MANAGEMENT
ROLE

		<u>MANAGEMENT</u> <u>ROLE</u>	
		<u>Advisory</u>	<u>Lead & Decision</u>
A.	<u>Construction of Protocol</u>		
1.	Definition of clinical objectives	NASA	HSMHA
2.	Definition of technological objectives	HSMHA	NASA
3.	Definition of clinical procedures	NASA	HSMHA
4.	Definition of technological manpower, hardware and software	HSMHA	NASA
5.	Definition of clinical evaluation procedures	NASA	HSMHA
6.	Definition of technological evaluation procedures	HSMHA	NASA
7.	Definition of overall systems management and systems evaluation using measures characteristic of systems analysis	HSMHA	NASA
B.	<u>Project Management</u>		
1.	Selection of clinical team and site	NASA	HSMHA
2.	Selection of communications hardware and engineering team	HSMHA	NASA
3.	Project management of clinical team	NASA	HSMHA
4.	Management of communications installation, operation, maintenance and alteration	HSMHA	NASA
5.	Evaluation of clinical results	NASA	HSMHA
6.	Evaluation of hardware configurations and operation	HSMHA	NASA
7.	Overall systems analysis and evaluation	HSMHA	NASA
8.	Formulation of conclusions regarding value and characteristics of a video system in the clinical setting chosen	NASA	HSMHA

C. Project Funding

- | | |
|---|-------|
| 1. Clinical facility and staff | HSMHA |
| 2. Engineering personnel and services | NASA |
| 3. Purchase and operation of video hardware | NASA |
| 4. Provision of medical consultation | HSMHA |
| 5. Provision of engineering consultation | NASA |
| 6. Publication of results | HSMHA |

APPENDIX E

A PROPOSAL TO
AUTOMATE THE DETERMINATION OF ANTIBIOTIC
SUSCEPTIBILITIES USING THE FIREFLY
LUCIFERASE ASSAY FOR
ADENOSINE TRIPHOSPHATE

NASA Goddard Space Flight Center
Greenbelt, Maryland

and

New England Medical Center
Boston, Massachusetts

April 1972

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INTRODUCTION

Optimum use of antimicrobial agents depends upon knowledge of the susceptibility of the infecting organism. Although this can sometimes be predicted from ancillary factors such as the general behavior of the bacterial species involved, the only reliable approach in most cases is that of direct measurement of the interaction between the organism and the drug. When this information is not readily available, the physician is faced with the option of polypharmacy, frequently entailing the use of toxic agents or educated guesswork which may eventuate in uncontrolled infection.

Present techniques of antibiotic susceptibility testing generally require 48 hours. Infected material is first plated on agar, then colonies are selected and studied by a standard (e.g. Kirby-Bauer) 18-hour susceptibility test. This proposal describes basic studies, field trials and automation of a method of susceptibility testing of acute urinary tract infections that could offer the following advantages:

- (1) Determination of antimicrobial susceptibilities within 3 to 4 hours, rather than the 48 hours occupied by the usual laboratory procedure or the 24 hours required if an initial isolation step is omitted
- (2) Rapid evaluation of the possibility of synergism or antagonism between agents. (The usual "checkerboard" (Sabath, 1968) or growth curve (Jawetz, 1968) procedures for such studies are very time and labor consuming. Also, patients are frequently given several antibiotics with little knowledge of their potential unfavorable interaction.)
- (3) Possible application to spinal fluid and blood, permitting earlier recognition of the presence of infection and rapid evaluation of susceptibility of the organism
- (4) Compatibility with automation

In summary, if the basic studies and field trials are successful, the techniques will permit rapid selection of an appropriate antibiotic for acute urinary tract infections, eliminate the need for guesswork polypharmacy, minimize the use of unnecessary toxic agents, and perhaps indicate whether a combination of drugs would be beneficial, neutral, or deleterious in the particular circumstance.

A potential method for the rapid determination of susceptibility of bacteria to antibiotics is described herein. The object of the proposed work is to verify the applicability of the method, to devise and automate the chemical process, and to obtain comparative data between the resulting rapid automated method and currently used methods.

Briefly the method involves the measurement of the increase in quantity of bacteria over a period of time in samples treated with antibiotics and the comparison of this increase with the increase in control samples from the same specimen. The relative difference is a measure of the susceptibility or resistance of the particular bacterium in that specimen to each antibiotic.

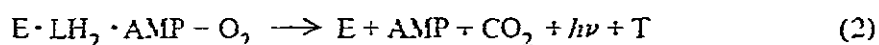
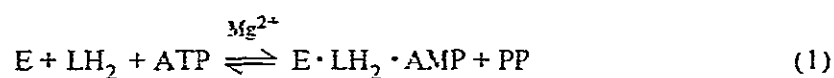
This quantitation will be done by measuring the amount of bacterial adenosine triphosphate (ATP) present in the sample by measuring the light produced in the reaction of the enzyme firefly luciferase with ATP. The entire process required to prepare the sample for this assay, perform the assay, and record the results can be automated. The luciferase reaction is well characterized and dependable, and a similar process has been automated for the detection of bacteria in urine as discussed in a later section.

A preliminary study by the proposers has indicated that determination of microbial susceptibilities to antibiotics of a single species can be resolved in 3 hours (See appendix). The assay for bacterial ATP takes less than 15 minutes per sample and is currently automated to produce one assay per minute.

CHEMICAL CHARACTERISTICS OF THE ASSAY FOR ATP

The ubiquity and functional significance of ATP in metabolism allows its assay to be an excellent monitor of the amount of biological material in a specimen. Because it was established that the firefly luciferase reaction, where light is produced by an enzymatic reaction, is specific for ATP many investigators use this reaction to determine the amount of bacteria or biological mass present in a specimen (Beutler and Mathai, 1967; Brewer and Knutsen, 1966; Cole et al., 1967; Ebadi et al., 1971; Freese et al., 1969; Holm-Hansen and Booth, 1966; Lee et al., 1971; Patterson et al., 1970)

The reaction mechanism and kinetics have been determined by several investigators (McElroy et al., 1969; Strehler and McElroy, 1957). The reaction can be summarized in two steps (Plant et al., 1968).



where

E = firefly luciferase

LH₂ = reduced luciferin

AMP = adenosine monophosphate

PP = pyrophosphate

T = thiazolinone (dehydroluciferin)

hν = light (550 nm)

Conditions have been prescribed where this enzymatic reaction can be used as a rapid, sensitive, and easy-to-use assay for the quantity of bacteria (Chappelle and Levin, 1964). When all reagents are present in excess, the light production is proportional to the ATP concentration, which is proportional to the bacterial cell concentration in the specimen. The plot of bacterial cell concentration versus light units shows a linear response over a functional range (Chappelle and Levin, 1968).

The ATP content of an average bacterium is 2.5×10^{-10} μg per organism. The ATP content varies somewhat through a growth cycle (Freese et al., 1969; Klotz et al., 1969) and varies with species from 0.28 to 8.9×10^{-10} μg for the 19 species tested (Chappelle and Levin, 1968).

One of the major problems in determining the relationship between ATP levels and bacterial cell number is the presence in the sample of large quantities of soluble ATP. Additionally, there may be numbers of nonbacterial cells containing ATP such as blood and other tissue cells. These amounts of ATP would far exceed the bacterial ATP levels in specimens such as blood and urine.

A method has been developed to chemically remove the ATP associated with non-bacterial cells and any soluble ATP (Picciolo et al., 1971). Treating the specimen with a nonionic detergent selectively ruptures mammalian cells and does not disturb the cell membranes of bacteria. The addition of an ATPase then hydrolyzes all the free ATP. This action is then inhibited, the bacterial cells are ruptured, and their ATP assayed by the luciferase light reaction.

PAST AND PRESENT WORK WITH THE ATP ASSAY

This proposal to automate the rapid determination of antibiotic sensitivities is a direct outgrowth of work done by NASA in the field of automated detection of extraterrestrial life. In the 1960's the Space Biology Branch of Goddard Space Flight Center was working intensively on this problem. There were three main tasks:

- (1) Determination of a parameter whose presence or absence would be a relatively universal indicator of the presence of life forms
- (2) Development of techniques for the detection of this parameter in the presence of interfering substances
- (3) Automation of these techniques so that the assay could be performed with high reliability in remote locations

The chosen parameter was the presence of ATP, and several methods of extraction of ATP from the sample under investigation were developed (Chappelle and Levin, 1968, Klofat et al., 1969, MacLeod et al., 1969).

The specific requirement for ATP in the bioluminescent firefly luciferase/luciferin reaction served as the basis for a quantitative assay of the extracted material. The final step was the construction of highly sensitive and reliable instrumentation for the detection and quantization of low-level light emissions (Chappelle and Levin, 1966). The amount of ATP per organism was determined for several species of bacteria (Chappelle and Levin, 1968) as was the ATP per organism for a single species at various stages of its growth phase (Freese et al., 1969).

A second method involving the detection of flavin mononucleotide with a similar specific bioluminescent assay was developed as an alternative approach (Chappelle et al., 1967, Chappelle and Picciolo, 1970, Picciolo et al., 1968). (This work has some interesting potential applications in the area of quantitative assays for vitamin B₂.)

While this work was underway, personnel from the Space Biology Branch were also working in collaboration with researchers at NIH on the description of sporulation mutants and the determination of the site of their metabolic blocks by the ATP assay (Freese et al., 1969; Klofat et al., 1969).

Potential applications of the ATP assay technology became of increasing interest to the GSFC proposers. In early 1969 they began an investigation of the use of the ATP assay to automate some portions of the workload in bacteriology laboratories in conjunction with the Johns Hopkins Hospital Laboratory of Clinical Medicine (Dr. Rex Conn). In 1970 a

method for the rapid detection of bacteria in urine specimens was developed (Picciolo et al., 1971). Some work on the application of this technique to the detection of bacteria in blood and spinal fluids has also been done. A prototype instrument that completely automates all phases of the assay for urine specimens has been constructed and is currently being tested in conjunction with Johns Hopkins Hospital.

A proposal for support of this work was submitted to the Kidney Disease Control Program of the Public Health Service. An interagency agreement has been negotiated under which funds to support this project have been transferred from PHS to NASA. These funds are then used by NASA to reimburse certain of the costs of Johns Hopkins Hospital in conjunction with this project.

Preliminary trials of the ATP assay procedure for urine have shown good correlation with results obtained via the streak-plate culture method at the Johns Hopkins Hospital (Picciolo et al., 1971). For those cases in which the spread-plate colony count was reported as 10 000 or more (the level considered clinically significant (Kass, 1956)), the ATP assay correlated well. However, two areas of differences appeared. The bacterial cell numbers obtained with the ATP assay were orders of magnitude higher than the plate count. Also, in 20 percent of the cases reported negative by plate count, ATP assay detected significant numbers of bacteria. The ATP assay correlated well, however, with the total microscopic counts. When more exhaustive measures were used to culture the bacteria (pour plate, additional kinds of growth media and anaerobic culture using prereduced media) a closer correlation between the colony counts and ATP assay of cell number was obtained. Thus, there appears to be a substantial number of urine specimens containing bacteria that do not culture via the standard streak-plate method.

An investigation of anaerobic bacteria in urine has been started in conjunction with Virginia Polytechnic Institute's Anaerobic Laboratory (Dr. Walter E. C. Moore and Dr. Lillian V. Holdeman). Preliminary results indicate that there are substantial numbers of anaerobic bacteria present in approximately one-half the cases where a discrepancy was found. Additional studies of this question are planned as part of the clinical trial of the automated instrument.

A review of this work on the rapid detection of bacteria in biological specimens was done by the National Academy of Engineering's Committee on the Interplay of Engineering With Biology and Medicine. Following this review, Dr. David Rutstein of the Harvard Medical School suggested that this technology could be applied to the rapid determination of antibiotic susceptibilities. A brief preliminary study has shown that a real possibility exists for this application. (See appendix.) The enclosed proposal is being submitted to obtain support for a more complete investigation.

SCOPE OF THE PROPOSAL

The proposed work to develop and automate the procedure for the determination of susceptibility of bacteria from infected urine specimens to antibiotics can be performed in several phases that will require 3 years to complete. The proposed schedule is shown in Figure 1. This section of the proposal will outline the phases; they will be discussed in detail in the next section.

PHASE 1. DEVELOPMENT OF THE ASSAY PROCEDURE

In the development of a method to determine susceptibilities, two types of infected urines will be considered: those infected with one species of bacterium and those infected with more than one species. Data will be obtained on the handling of these to determine a procedure for accurately choosing the antibiotic to which the organisms are susceptible.

It will be necessary to investigate some basic areas that could affect the validity and efficiency of the technique, such as the changes in intracellular ATP brought about by the antibiotic, the use of growth medium to reduce the time required for the analysis, the influence of the growth phase on the analysis time, the effect of the presence of more than one species in the sample on the ability to determine a susceptibility pattern, and the interaction of antibiotics. After determination of the optimal conditions, a biochemical

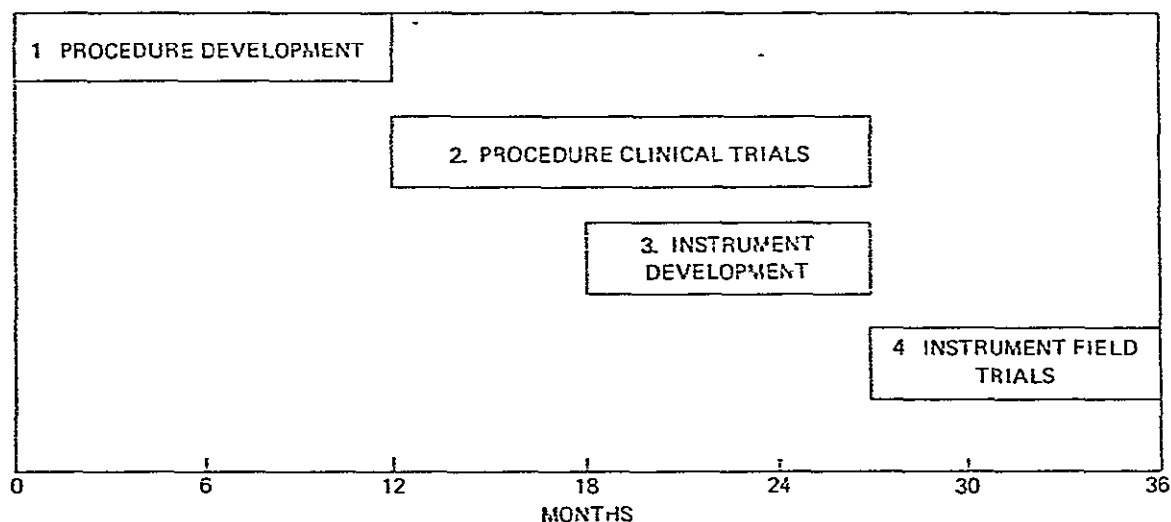


Figure 1—Proposed schedule for the development and automation of the determination of antibiotic susceptibilities using the firefly luciferase assay for adenosine triphosphate

procedure will be developed to measure the changes in the ATP in actively growing bacteria from urine when treated with different concentrations of different antibiotics

PHASE 2. DEMONSTRATION OF THE VALIDITY OF THE PROCEDURE

The procedure will be tested by correlating the results obtained with those from a standard method of susceptibility determination. An evaluation of the impact that this method has on patient care will then be made.

PHASE 3. AUTOMATION OF THE PROCEDURE

A preliminary design of the automation will be begun during the procedure development phase. A prototype instrument that will automate the procedure for use in a clinical laboratory will then be fabricated and checked out.

PHASE 4. FIELD TESTS OF THE AUTOMATED INSTRUMENT

The instrument will be operated in a clinical laboratory to validate its operation and accuracy; the results will be compared with those from the standard methods.

EXPERIMENTAL PROCEDURE

PHASE I. DEVELOPMENT OF THE ASSAY PROCEDURE

Standard methods of antibiotic susceptibility determinations involve the growth of the bacteria in the presence of the antibiotic and some measure of the increase in the number of cells. Antibiotics inhibit growth of cells by various means, such as interfering with cell wall synthesis, protein synthesis and RNA or DNA synthesis. However, it is not known whether antibiotics directly affect the levels of intracellular ATP. This must be determined in order to develop an assay whereby ATP levels measure the changes in cell numbers.

Also, optimal conditions for growth, antibiotic treatment, and assay for ATP must be determined.

It is proposed, therefore, to assay various urine specimens to determine the properties and problems associated with urines, to determine the changes in intracellular ATP after treatment with antibiotics, and to determine the optimal conditions for the assay. Based on the results of this experimentation, a protocol for the use of the luciferase ATP assay for the determination of antibiotic susceptibility of bacteria will be established and documented.

Study of Infected Urines for Antibiotic Susceptibilities

Patients who have acute urinary tract infections will be selected by the following routine. Each morning, aliquots will be taken from urine specimens received by the clinical bacteriology laboratory for culture and sensitivity, and assayed for ATP content. In the case of those that are positive (indicating significant bacteriuria), the patient's chart will be reviewed to determine whether the patient is taking antibiotics or if there is reason to suspect multiple infecting agents (e.g., the patient with recent cultures positive for more than one species or the patient on chronic catheter drainage). For the first part of the study, such patients will be excluded.

From the suitable specimens remaining, samples will be taken, added to broth culture, and incubated at 37° C for approximately 1 hour so that organisms will enter the growth phase. The details of inoculum size to be used, specific broth medium, and initial incubation period will be modified according to preliminary study results. Because the vast majority of potential pathogens will grow well in trypticase soy broth, this will be among the broths tested in the system. In addition, it is intended to further explore the possibility of using urine itself, or a similar solution, as a medium for the whole experiment.

The culture will then be divided into aliquots to compare the rate of growth (measured by ATP production) in the presence of high and low concentrations of antibiotic and in the

absence of antibiotic. The concentrations of drug have been selected to approximate those attainable in serum (low concentration) and urine (high concentration) using reasonable dosage regimens. The following antibiotics will be added to the aliquots to produce the final concentrations indicated.

<u>Antibiotic</u>	<u>Low Concentration ($\mu\text{g./ml}$)</u>	<u>High Concentration ($\mu\text{g./ml}$)</u>
Cephalothin	10	1000
Ampicillin	2	200
Penicillin G	2	200
Tetracycline	2	200
Sulfisoxazole	100	1000
Streptomycin	10	1000
Gentamicin	10	50
Kanamycin	10	50
Erythromycin	10	50
Chloramphenicol	10	100

Saline will be added to two aliquots of each urine sample to serve as controls. Specimens will then be incubated at 37° C.

At the time of addition of antibiotics (baseline or 0 hour) and 3 hours later, specimens will be assayed for ATP content by the luciferase method. For each aliquot, baseline and 3-hour ATP concentrations will be compared with the values for controls. Where there is no increase in ATP concentration over the baseline value, the micro-organism will be considered (initially) as susceptible to the antibiotic; those in which the increase in ATP concentration is similar to that in controls will be considered resistant; any intermediate results will be so recorded.

Comparison will then be made with the results obtained for the same urine specimen by the bacteriology laboratory using the Kirby-Bauer susceptibility assay. Where discrepancies occur, these will be investigated, by repetition of tests and by assays done on micro-organisms in pure culture.

The foregoing approach will be modified in accordance with the results of these preliminary basic studies, especially as regards to interference of antibiotic, medium and growth-cycle phase with the assay. In addition, the concentrations of antibiotic that most faithfully reproduce the results obtained by the routine culture-sensitivity method will be determined. Finally, the patient's response to therapy will be followed and correlated with the results from the two different methods.

Initial efforts will be directed to acute urinary tract infections due to a single micro-organism. As familiarity is gained with this approach, studies will be made of urinary infections involving two or more micro-organisms. In addition, the techniques will be applied to the examination of spinal fluid and blood.

Effects of Antibiotics on the Amount of ATP per Cell

The experiments are based on the assumption that increases or decreases in the concentration of ATP reflect parallel changes in numbers of viable bacteria. It is possible,

however, that, in the presence of certain antibiotics, the measured ATP will not reflect comparable changes in the number of viable cells. One way in which this could occur would be if the antibiotic had no inhibitory effect on bacterial growth but did cause a decrease in ATP per cell. A second possible way would be if cellular ATP increased while bacterial growth was inhibited by the antibiotic. The magnitude of this second condition would depend upon the half-life of ATP in nondividing and dead bacteria.

The existence of such conditions will be ascertained in a variety of bacterial species for each of the antibiotics. Bacterial ATP concentration measured by the luciferase assay after treatment of cells with the antibiotic at different stages in the life cycle will be related to both total cell count (microscopic) and viable colony count. ATP per cell as calculated from both total count and plate count will then be compared with standard ATP cell values obtained from cultures grown without antibiotics.

A cellular ATP value in excess of the standard value on the basis of plate count would indicate that either "nonculturable" cells were contributing ATP or that the antibiotic was eliciting an increase in cellular ATP. If the cellular ATP was in excess of the standard value on the basis of a total cell count, this would definitely show an increase in ATP per cell. A decrease in cellular ATP would be concluded if the ATP per cell on the basis of plate count was less than the standard cell value. The lifetime of ATP in a nondividing cell will be determined by following the decay of ATP in antibiotic cultures where growth has ceased.

Effect of the Phase of the Bacterial Growth Cycle on Antibiotic Susceptibility

The major goal is to develop an assay that will reduce the time now required to determine susceptibility patterns. The ability of micro-organisms to increase in number will depend on their available nutrients. The differences in ATP levels between the controls and the aliquots containing an antibiotic to which the species is sensitive will be greater when the controls are growing at a faster rate and when there are fewer ATP-containing, but nondividing cells. Bacteria that occur in heavily infected urine specimens may be in the stationary phase of their growth cycle where there is little net increase in cell number with time.

A definition of these effects will be made by the culture of pure species throughout a complete growth cycle. Aliquots will be removed at various times and incubated with various antibiotics. The ATP assay will be made on these aliquots and the incubation time required to determine susceptibilities will be determined. The effects of adding nutrients to the urine specimens directly will also be investigated. A selection of media will be made to encompass the requirements for the majority of organisms associated with infected urines. Various media will be added to the organisms in the presence of sterilized urine, and the incubation time will be determined that is necessary to resolve differences in the ATP content of aliquots of cells in the presence of antibiotics and in the controls. The best growth conditions will then be selected.

2-2

Determination of Susceptibilities in Mixed Cultures

Mixed bacterial species are frequently found in urine specimens from patients with chronic urinary tract infections. With specimens of this type, current susceptibility techniques require the prior isolation of the individual species. Although it may ultimately be necessary to include this initial isolation step in the ATP procedure for mixed cultures, we will first investigate means for circumventing this step thus reducing analysis time.

Inasmuch as the successful treatment of a multiple organism infection requires either a broad spectrum antibiotic or a mixture of antibiotics, susceptibility tests on mixed cultures would only require the determination of which mixture would be effective. This could possibly be accomplished without isolating each bacterial component in the mixed culture. The procedure investigated will be as follows:

Urine specimens will be obtained from patients with a possible multiple infection. These specimens will be treated for susceptibility in the same fashion as was described for single organism infections. Additional specimens will be obtained from those patients whose urinary bacteria showed incomplete susceptibility to more than one antibiotic and complete susceptibility to none. These specimens would be initially cultured as before but subsequently incubated with all of the possible combinations of the antibiotics previously shown to be partially effective. (It can be calculated that the possible combinations would become excessively high if more than about five different species were present.) This should allow the determination of the minimal number of antibiotics required for complete growth inhibition.

The feasibility of this approach will be determined on the basis of its correlation with results from the routine laboratory where the individual species will have been isolated and susceptibilities determined. If our approach is valid, the antibiotics of the minimal mixture should be the same as those found to be capable of completely inhibiting the growth of the individual species.

Antimicrobial Synergism and Antagonism

A variety of techniques for the determination of antibiotic synergism and antagonism are available, and the interactions of broad groups of antibiotics have been investigated with respect to certain bacterial species (Sabath, 1968; Jawetz, 1968). The techniques are so time consuming and laborious that they are restricted, at present, to use in research laboratories and in unusual circumstances such as refractory cases of bacterial endocarditis and meningitis. Thus, although it is known that many antibacterial and other agents interact both synergistically and antagonistically with one another, technical limitations preclude study of this important phenomenon in the majority of patients. The ATP assay is ideally suited to such studies, providing rapid and easy assay of changes in bacterial numbers over short time periods.

By the same method of studying infected urines for antibiotic susceptibilities as described previously, mixtures of antibiotics could be studied and the results interpreted in

the same manner. Initially, the reference point for testing the validity of the results will involve the performance of pour-plate colony counts in parallel with the ATP assays. Where possible, clinical response will be noted in those patients to whom antibiotic combinations are actually given.

If this technique for the assessment of antibiotic synergism and antagonism proves workable, it will provide a major investigative and therapeutic tool in an area that is generally neglected. The technique would be applicable not only to organisms infecting the urinary tract, but to cultures from any site. In addition, where mixed cultures are obtained, the same techniques would be used to evaluate the efficacy of a combination of antibiotics against the mixture of micro-organisms. The drugs included in the mixture need not be restricted to antibiotics; such agents as steroids, salicylates, immunosuppressives, and other agents could be included.

PHASE 2. DEMONSTRATION OF THE VALIDITY OF THE PROCEDURE

The final procedure will be validated by conducting field trials on specimens handled routinely by the hospital and correlating the results of the ATP assay with those obtained by standard susceptibility testing methods. Patient information will be obtained and analyzed for the relationship between the assay results and the effectiveness of the administered antibiotic.

PHASE 3. AUTOMATION OF THE PROCEDURE

The Food and Drug Administration has recommended that 18 antibiotics be used for screening in susceptibility testing (*Federal Register*, 1971). Such a large number requires that simple and efficient methods be used, including some degree of automation. Throughout the development of this procedure, compatibility with automation will be a prime goal. After deciding the degree of automation that is required in the face of economy and complexity tradeoffs, a prototype instrument will be designed, fabricated, and tested.

The requirements will include discrete specimen processing to insure no carryover among specimens, uniform distribution of the specimen to the replicate incubation vessels, and precise dilution and distribution of the drug to the incubation vessels. Parts of the instrument must allow sterilization and maintenance of sterile conditions during growth. Materials must be chosen that are compatible with the chemicals used in the system.

PHASE 4. FIELD TESTS OF THE AUTOMATED INSTRUMENT

After the electronic, mechanical, and chemical operations of the instrument have been checked, selected field trials will begin. Comparisons will be made between the results from the automated instrument and those from standard methods of susceptibility testing. Discrepancies will be investigated. The final results will be statistically analyzed and the validity and performance of the instrument evaluated. When proven successful, the instrument will be commercialized by contacting interested industrial concerns.

DIVISION OF RESPONSIBILITIES

This is a joint proposal of GSFC and NEMC. With one exception, people from both organizations will be involved to some extent in every phase of the project. The one exception is that all decisions relating to patient care arising from this project will be the sole prerogative and responsibility of the NEMC staff. The areas of primary responsibility for each of the two organizations are discussed in the following paragraphs in relation to the four phases of the project.

PHASE 1 DEVELOPMENT OF ASSAY PROCEDURE

This phase will be conducted at both locations. The work primarily involving fundamental knowledge of the effects of antibiotics on intracellular ATP will be conducted mostly at Goddard by GSFC personnel and by a hospital-supplied medical technologist. The work involving application of trial procedures to urines will be mostly done at NEMC by their personnel.

During this phase, some of the NEMC personnel will be working at GSFC to assist in the definition of the fundamental studies and to become familiar with the ATP assay procedures. Similarly, GSFC personnel will be working at NEMC to assist in establishing test procedures and to gain familiarity with the hospital laboratory procedures and problems in this area.

GSFC will provide supplies, chemicals, laboratory space, and instrumental support for all personnel from both organizations while they work at GSFC. NEMC will provide supplies, chemical laboratory space, and instrumental support for all personnel during their stay at NEMC.

PHASE 2 DEMONSTRATION OF THE VALIDITY OF THE PROCEDURE

Clinical trials of the procedure will be carried out at NEMC with the help of GSFC personnel as needed, especially for training in the handling of the chemistry of the luciferase ATP assay. Both groups will evaluate the results and make necessary modifications of the procedure.

PHASE 3 AUTOMATION OF THE PROCEDURE

Design, fabrication, and checkout of the automated instrument will be primarily GSFC responsibility.

PHASE 4. FIELD TESTS OF THE AUTOMATED INSTRUMENT

Personnel will learn to operate the instrument at GSFC; field trials of the automated instrument will be conducted at NEMC.

PHASE 4. FIELD TESTS OF THE AUTOMATED INSTRUMENT

Personnel will learn to operate the instrument at GSFC, field trials of the automated instrument will be conducted at NEMC.

FUNDING

An interagency agreement providing for transfer of funds will be executed between the National Aeronautics and Space Administration and the cooperating agency. NASA will then execute a cooperative agreement with NEMC to cover their participation in the amount of \$41 800 for the first year.

FUNDING FOR FIRST YEAR

GSFC operations No funding is required for GSFC salaries or overhead. However, other items are required and estimated as follows for the first year

(1) Laboratory supplies such as automatic pipetting devices, magnetic mixers, disposable pipettes, and test tubes	\$ 5 000
(2) Chemicals and biochemicals such as apyrase, perchloric acid, buffers, luciferase	6 000
(3) Medical technologist to assist in development of procedure at GSFC To be supplied by participating medical institution under cooperative agreement	10 000
(4) Instrumentation support from the GSFC Fabrication Division for design, fabrication, and hardware procurement	5 000
(5) Consultants' fees for such problems as those with anaerobic culture	1 000
(6) Travel funds for GSFC personnel to work at NEMC consisting of two persons visiting NEMC for 1 week, 10 times	<u>5 000</u>
Total	<u><u>32 000</u></u>

NEMC operations:

(1) Salaries.	
Technician	8 000
Fellow in Infectious Disease (full salary)	12 000
Dr Michael Barza (1/3 salary)	6 000

(2) Equipment	
Glassware, media, syringes, disposable pipettes, etc.	2 500
Laboratory equipment such as heating bath, incubator, mixers, diluting and dispensing equipment	500
Light measuring equipment	2 000
Luciferase, apyrase, and other reagent ingredients	5 000
(3) Travel funds to work at GSFC	<u>2 000</u>
Subtotal	38 000
Overhead (10 percent)	<u>3 800</u>
Total	<u>41 800</u>
Total cost of operations for the first year	<u><u>\$73 800</u></u>

FUNDING FOR SECOND YEAR

GSFC operations.

(1) Laboratory supplies	\$ 2 000
(2) Medical technologist	10 000
(3) Chemicals	3 000
(4) Fabrication of automated instrument	24 000
(5) Consultant fees	1 000
(6) Travel	<u>5 000</u>
Total	<u><u>45 000</u></u>

NEMC operations

(1) Salaries	
Technician	8 000
Fellow in Infectious Disease	12 000
Dr Michael Barza	6 000
(2) Supplies	5 000
(3) Travel	<u>1 000</u>
Subtotal	32 000
Overhead (10 percent)	<u>3 200</u>
Total	<u><u>35 200</u></u>
Total cost of operations for the second year	<u><u>\$80 200</u></u>

FUNDING FOR THIRD YEAR

GSFC operations

(1) Supplies	\$ 1 000
(2) Medical technologist	10 000
(3) Chemicals	1 000
(4) Fabrication of automated instrument	6 000
(5) Travel	<u>5 000</u>
Total	<u>23 000</u>

NEMC operations:

(1) Salaries	
Technician	8 000
Fellow in Infectious Disease	12 000
Dr. Michael Barza	6 000
(2) Supplies	5 000
(3) Travel	<u>1 000</u>
Subtotal	32 000
Overhead (10 percent)	<u>3 200</u>
Total	<u>35 200</u>

Total cost of operations for the third year	<u>\$58 200</u>
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Appendix

FEASIBILITY STUDY

To determine the range of problems that might be encountered in applying the firefly luciferase assay for ATP to antibiotic susceptibility testing a preliminary (4-day) study was run on urine specimens from patients with chronic infections. Fresh specimens were obtained from the paraplegic ward of the Veterans' Hospital, Boston, Mass.

An initial growth experiment determined that after an initial lag phase of up to 3 hours, three species of bacteria doubled four to five times in the next 3 hours when inoculated from broth into sterilized urine and incubated at 37° C (See Table A1.) This indicates that urine will support growth of these bacteria, however, a long lag phase may not allow a detectable difference in ATP levels within a short incubation time. -

Table A1--Number of doublings during incubation interval.

Bacteria	0 to 3 Hours	3 to 6 Hours
<i>Proteus</i>	1 to 2	4 to 5
<i>Klebsiella</i>	3	4
<i>E. coli</i>	1 to 2	5
<i>Pseudomonas</i> ^a	0	0

^aTurbid after 12 hours.

It was necessary to determine whether the antibiotics themselves inhibited the ATP response. We assayed ATP in the presence of 10 antibiotics in the highest concentrations to be used. Only three showed some inhibition. tetracycline, 36 percent, gentamicin 20 percent, kanamycin, 10 percent. The other noninhibitory antibiotics tested were ampicillin, erythromycin, streptomycin, penicillin G, chloramphenicol, cephalothin, and sulfisoxazole.

Five infected urine specimens were then assayed. Aliquots were distributed into growth tubes, antibiotics were added to each growth tube, water was added to the controls and the tubes were incubated at 37° C for 3 hours. Aliquots were assayed for bacterial ATP at inoculation and at 3 hours. In most cases there was no significant increase in the ATP in the control tubes in this 3-hour interval. However, it was noted that the initial amount of ATP was so high that it is suspected that the cells were in maximum stationary phase where no increase in cell number could occur. Thus, another approach would be necessary in which the controls would grow at a sufficient rate in the infected urine.

A second set of infected urines were run. These were filtered through glass wool before testing to reduce the number of organisms at the initiation of incubation. This approach

was partially successful because there was an increase in the ATP levels in the controls from the initial time to 3 hours. However, the culture method showed several species in each urine, and, therefore, the ATP results were inconsistent.

A colony (*Klebsiella*) was picked from an isolation plate from an infected urine and inoculated into broth and into sterilized urine. After 3 hours of incubation, a sixfold increase in the ATP levels in the control urine was detected while an eightfold increase occurred in the broth culture. In this case, the susceptibility pattern was the same as that obtained by the disk method, except for one antibiotic in broth, ampicillin. High and low concentrations of each antibiotic were run; the pattern was consistent with the detection of a dosage effect of the antibiotic. See Table A2.

This close agreement and the magnitude of the differences in the ATP levels in the controls after 3 hours encourages us to believe that this method can eventually be optimized to obtain accurate and significant results of susceptibilities in a short period of time. The development of this technique will depend on some method to handle mixed cultures, to increase the growth rate, and to account for the effect of the antibiotic itself on the bacterial ATP levels independent of growth.

Table A2--Comparison of *Klebsiella* susceptibility patterns by the disk method and by the measurement of bacterial ATP levels by the firefly luciferase method ^a

Antibiotic	Disk Method		ATP Assay						
	Drug Concentration ($\mu\text{g}/\text{disk}$)	Result ^b	Drug Concentration ($\mu\text{g}/\text{ml}$)	Broth			Urine		
				Result ^b	ATP Level		Result ^b	ATP Level	
					t_0	t_3		t_0	t_3
Ampicillin	10	R	200	S	12	33	S	44	6
			2	S	24	37	R	50	120
Erythromycin	15	R	50	R	28	130	S	38	27
	2	R	10	R	10	1000	R	21	110
Tetracycline	30	R	200	R	13	300	R	33	110
	5	R	2	R	26	1800	R	35	120
Gentamicin	10	S	50	S	5	21	S	4	9
			10	S	7	8	S	8	7
Chloramphenicol	30	S	100	S	31	45	S	42	15
	5	R	10	S	23	37	S	25	11
Cephalothin	30	S	1000	S	15	23	S	33	10
		R	10	S	21	23	R	33	90
None				Control	18	1600	Control	39	140
					20	1750		14	150

^aThe ATP was measured at t_0 = initial time and at t_3 = 3 hours.

^bR = resistant, S = sensitive

^cThis low initial measurement is assumed to be due to the inhibition caused by the antibiotic itself in the assay

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APPENDIX F

Technical Characteristics of the Firefly Luciferase Assay for the Determination of Bacteria in Biological Fluids

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March 25, 1973

Introduction

After 10 years of research on the firefly luciferase assay for the measurement of adenosine triphosphate, we find that there are always ways to adapt the assay to solve problems in other applications. We consider that we have a cadre of knowledge and experience that describes a basic method for measuring pico amounts of ATP, small numbers of bacteria, and other types of living cells in the presence of inhibitors and extracellular ATP. Additionally, bacterial ATP can now be distinguished from soluble and blood cell ATP.

Currently, we are engaged in working out modifications of this basic procedure for use in medical applications. As different types of clinical specimens are assayed for the presence of bacteria, problems arise that call for biochemical or physical changes in the assay technique. The modified technique is again tested in the clinical situation.

A. Currently Used Procedures

Two modifications of the basic luciferase assay are presented for the quantitative detection of bacteria by the luciferase assay for ATP. One is a direct method (Procedure 1 - Non-centrifuged); the other is a concentration method using centrifugation (Procedure 2 - Centrifuged).

B. Linearity and Sensitivity

The linearity and sensitivity of the assay for known amounts of ATP was determined when ATP was diluted in three solutions: saline, trypticase soy broth and pooled, filtered urine.

Procedure 1 Malic-Nitric Acid

Non-Centrifuged Method for Luciferase Assay of Bacteria

0.5 ml sample: Urine, bacteria, etc.

Add 0.1 ml apy-TX-Ca: 40 mg apyrase/ml 0.03 M CaCl_2 , 0.6% TX-100

wait 15 minutes vortexing frequently

Add 0.1 ml malic-arsenate: 0.5 M Malic Acid 0.005 M Sodium Arsenate, pH 3.75

wait 15 minutes vortexing frequently

Add 0.1 ml 1.5 N HNO_3

vortex well, wait 5 minutes

Add 4.2 ml sterile, deionized H_2O

Assay: Inject 0.1 ml of above into 0.1 ml of Luciferase (Dupont)

reconstituted with 1.5 ml 0.2 M Tris, 9.01 M MgSO_4 pH 8.0 per vial

Recovery: 0.05 ml of ATP (10^{-2} $\mu\text{M}/\text{ml}$) or 0.5 ml of ATP (10^{-3} $\mu\text{M}/\text{ml}$)

depending on desired accuracy of delivery is added to the remainder
of the treated sample

Procedure 2 Malic-Nitric Acid

Centrifugation Method for Luciferase Assay of Bacteria

10 ml sample: urine, bacteria, etc.

Add 0.2 ml 6% Triton X-100

vortex well

centrifuged at 12,000 RPM for 5 minutes at 20°C

decant inverted on filter paper for 5 minutes

Add 1.0 ml Apy-Ca: 10 ng apyrase/ml 0.03 M CaCl_2

vortex well

Add 5.0 ml Normal Saline (9%)

mix well

wait 15 minutes

Add 1.0 ml Malic-Arsenate: 0.25 M Malic-Acid 0.005 M Sodium Arsenate, pH 3.75

mix well

centrifuged at 12,000 RPM for 15 minutes, 20°C

decant on filter paper for 5 minutes

Add 0.2 ml 0.0625 N HNO_3

vortex well

wait 5 minutes

Add 0.2 ml sterile, deionized H_2O

Assay: Inject 0.1 ml of above into 0.1 ml of Luciferase (Dupont) re-

constituted with 1.5 ml 0.15 M Tris with 0.01 M MgSO_4 pH 8.0/vial

Recovery: 0.05 ml of ATP #3 (10^{-3} $\mu\text{M}/\text{ml}$) is added to the remainder of the treated sample

Table I shows the light response as a function of ATP concentration using the centrifugation and non-centrifugation procedures. On the basis of actual ATP injected, the light response for the two methods is approximately the same. It thus follows that in the centrifugation procedure where one injects the equivalent of 2.5 ml of original sample instead of 0.01 ml as in the uncentrifuged procedure, the overall sensitivity should increase by about 250 times. This is shown in the first column of Table I $\mu\text{M ATP/ml}$. The upper level of ATP which can be measured is limited by the saturation of the photocathode of the photomultiplier or by the concentration of other reagents, such as luciferase and luciferin. The lower level is limited by the blank level* which must be subtracted from each reading. One area of work is to develop a means of measuring a blank for each unknown sample or eliminating the blank. Since the nature of the sample can produce variation in blank levels, this is a very critical problem.

*Blank light is light emission observed when all constituents of assay are present except sample or ATP.

Table 1
Centrifuged Procedure

$\mu\text{M ATP/ml}$ Original Sample	$\mu\text{M ATP}$ Injected	Light Units		
		Saline	Broth	Urine
4.4×10^{-4}	1.1×10^{-3}	Saturated	Saturated	Saturated
4.4×10^{-5}	1.1×10^{-4}	62,000	58,000	54,000
4.4×10^{-6}	1.1×10^{-5}	6,000	6,000	6,500
4.4×10^{-7}	1.1×10^{-6}	600	550	600
4.4×10^{-8}	1.1×10^{-7}	58	70	54
4.4×10^{-9}	1.1×10^{-8}	28	15	7
4.4×10^{-10}	1.1×10^{-9}	2	4	0

Non-Centrifuged Procedure

1×10^{-2}	1×10^{-4}	45,000	55,000	52,000
1×10^{-3}	1×10^{-5}	6,500	6,500	5,400
1×10^{-4}	1×10^{-6}	700	600	530
1×10^{-5}	1×10^{-7}	61	45	44
1×10^{-6}	1×10^{-8}	22	5	9
1×10^{-7}	1×10^{-9}	2	0	4
1×10^{-8}	1×10^{-10}	4	0	9
1×10^{-9}	1×10^{-11}	0	0	3

In order to summarize the reproducibility and sensitivity of the assay for detecting bacteria, we ran the following experiment, where we determined Escherichia coli cell number by the luciferase centrifugation assay and the non-centrifuged assay, microscopic counting and agar plate colony counts. E. coli were grown to log phase in Trypticase soy broth, centrifuged and equal aliquots resuspended in normal saline, filtered, pooled urine and fresh trypticase soy broth. Microscopic and spread plate counts were run on all 3 aliquots. Serial dilutions were made on the three suspensions and Procedures 1 and 2 were run on the serial dilutions. The microscopic counts agreed closely with the plate counts indicating that all the bacteria were dividing and therefore were viable. Data in Table 3 gives the bacteria/ml of stock solution obtained by averaging the microscopic and plate counts, the coefficient of variation for each set of measurements, the ATP/ml stock solution, the number of bacteria/ml that gives a response of one unit above the blank value, and the average ATP per bacterium calculated from this experiment. The graphs in Figure 1 show the ATP/ml by the luciferase assay vs bacteria/ml by microscopic and plate counts.

The lowest number of cells which can be detected by the non-centrifuged procedure has been found to be between 5×10^5 and 1×10^6 depending on the species and media as compared with $3 \times 10^3 - 2 \times 10^2$ for the centrifugation procedure. In spite of the reduced overall sensitivity of the non-centrifuged procedure, it would be more applicable because of its simplicity in situations where the cell number is high, i.e. $>10^6$ and where the media does not contain luciferase inhibitors, e.g. pure cultures in defined growth media.

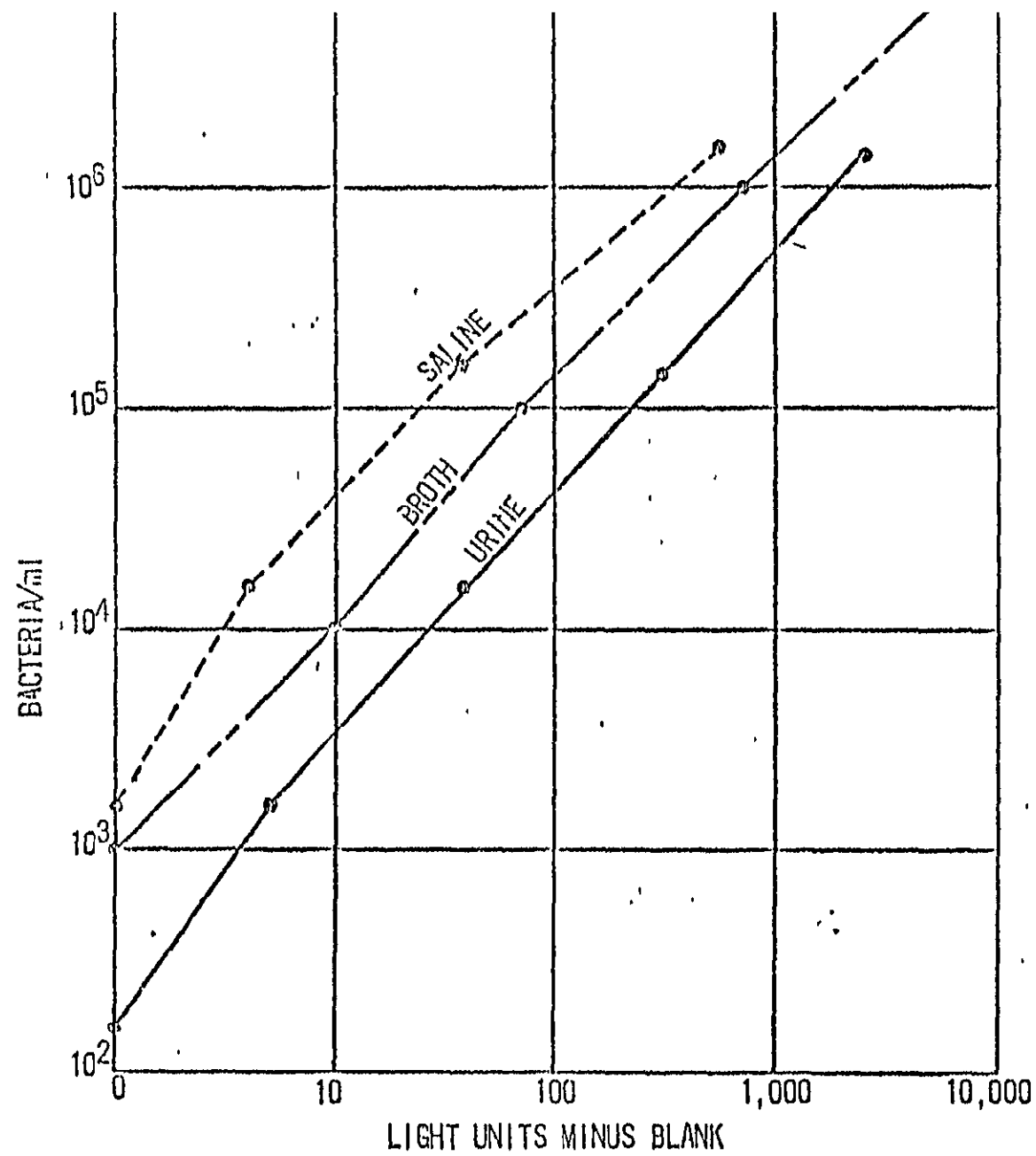


FIGURE 1
MALIC-NITRIC ACID CENTRIFUGED PROCEDURE

Table 2

Results from Centrifugation Procedure 2 with E. Coli in Saline,
Urine and Broth

	<u>Saline</u>	<u>Urine</u>	<u>Broth</u>
Average of microscopic and colony counts - bacteria/ml	1.6×10^8	1.6×10^8	1.9×10^8
Coefficient of Variation	18%	14%	19%
$\mu\text{M ATP/ml}$	3.0×10^{-5}	2.7×10^{-4}	5.4×10^{-4}
Coefficient of Variation	25%	25%	19%
Sensitivity-bacteria/ml	3.6×10^3	4.1×10^2	2.3×10^2
$\mu\text{M ATP/bacterium}$	1.8×10^{-13}	1.6×10^{-12}	2.8×10^{-15}

C. Inhibition

The presence of each of the assay reagents introduces inhibition of the luciferase activity in varying amounts. For a constant amount of ATP, % inhibition is given for each of the complete procedures when compared with a procedure with no inhibiting reagents included.

1. ATP in H ₂ O, Luciferase in 0.01 M Tris	0%
Non-centrifuged with Malic Acid	
2. ATP in saline	83.8%
3. ATP in urine	86.5%
Centrifuged with Malic Acid	
4. ATP in saline	83.8%
5. ATP in urine	81.1%

When it is expected that fluctuations will be introduced by the unknown samples, each sample must be evaluated for its inhibition. This is done by assaying the unknown then adding a negligible volume of standard ATP at a concentration far in excess of the sample ATP and repeating the assay. By this "recovery method", an exact correction can be made for all inhibitors, known and unknown in each sample. Data is given on the range of inhibition in selected urine specimens. The sample reading is subtracted from the recovery reading and then the ratio of sample reading to net recovery reading is equivalent to the ratio between the amount of ATP in the sample and the amount of ATP added to the recovery.

D. Interfering Substances

ATP is found associated with all living things and therefore some means of removing all non-bacterial ATP must be used in any assay system for bacterial ATP. We added an ATPase, (potatoe apyrase) to hydrolyse all free, soluble ATP. The total activity (8.8 units) of the apyrase is sufficient to remove 10^{-1} μ M ATP/ μ l of specimen in 15 minutes at 23°C. If samples are suspected of containing ATP in excess of this amount, the apyrase concentration should be appropriately increased. The presence of non-bacterial cells is a source of ATP also. We therefore treated the specimen with a non-ionic detergent (Triton X-100) to rupture blood cells. The optimal concentration (0.1%) of Triton X-100 will release all the ATP from a 20% solution of blood within 15 minutes at 23°C.

In special cases where more blood cell contamination is possible, reoptimization will be necessary. Other types of mammalian cells are believed to be even more susceptible to the TX rupture. Research is currently underway to verify this using tissue culture cells.

In our earlier work with dilutions of whole blood, it was found that there was residual amount of ATP remaining after treatment with TX and apyrase and subsequent treatment with an acid extractant. This was found to be removed by lowering the pH of the mixture after treatment with TX and apyrase to pH 3.5 for 15 minutes (Procedure 1). This is due to the release of ATP bound to factors such as protein and particulates. This is accomplished by a buffer, such as malic acid or glycine. Two disadvantages ensue by using the buffer: stronger acid extractant is required and the malic acid has a variable effect on the amount of ATP present within the bacterial cell. The stronger extractant is counteracted by using higher Tris buffer concentration in the luciferase.

However, this results in a decrease in sensitivity. The intrabacterial effect, however, is difficult to assess. We have seen from 0 to 30% decrease in ATP/bacterium using the malic acid in the non-centrifuged procedure, while allowing the removal of residual amounts of ATP. The effect can be reversed by bringing the bacterial suspension back to neutrality.

E. Concentration Methods

To overcome certain of the deficiencies described above, we are developing methods for concentrating the sample that will remove fluctuating and unknown inhibitors and reduce the amount of residual reagents that act as inhibitors, which should result in improved sensitivity, accuracy and precision. One method has been optimized using centrifugation (Procedure 2, Figure 1). The number of samples that can be processed in one batch is limited by the number of spaces in the centrifuge head. We are currently exploring the use of a multiple filtration system in order to eliminate the centrifugation time.

F. Efficiency

One of the goals in our approach is to streamline the daily operations to result in a technique that can be performed by relatively untrained personnel as well as requiring minimal set up time. To effect this, all reagents are prealiquoted into daily amounts and frozen. Luciferase and apyrase are lyophilized and rehydrated at use.

G. Application

Various biological specimens can be assayed for the presence of bacteria with proper understanding of the background and sensitivity problems involved in each type of specimen. Growth steps can be employed where the sensitivity requirements are stringent. The luciferase assay could then be used to reduce the time for detection of growth. Comparisons have been run on clinical urine specimens with the centrifuged luciferase assay compared with pour plate colony counts. Statistical analysis is currently being performed on this data. A sample of the results are shown in Table 3.

H. Cost

A cost-effective study will be undertaken shortly to evaluate the projected cost of the luciferase assay in comparison with other methods in clinical use. The major expendable reagents are the purified, lyophilized luciferase and apyrase which are commercially available. The amounts used in the centrifugation procedure cost about 80 cents per assay. Automation aspects will be considered in the study.

Table 3

A SAMPLE OF RESULTS FROM THE CENTRIFUGATION LUCIFERASE ASSAY PROCEDURE ON CLINICAL URINE SPECIMENS*

SPECIMEN #	BACTERIA PER ml	
	CENTRIFUGATION	COLONY COUNT
1	3.2×10^8	$>10^7$
2	3.1×10^4	4×10^3
3	$<10^3$	$<10^2$
4	$<10^3$	8×10^3
5	7.0×10^3	1×10^5
6	$<10^3$	$<10^2$
7	9.4×10^3	2×10^2
8	$<10^3$	$<10^2$
9	3.1×10^7	$>10^7$
10	3.1×10^7	$>10^7$
11	$<10^3$	$<10^2$
12	2.7×10^4	$<10^2$
13	8.4×10^7	$>10^7$
14	3.2×10^4	9×10^2
15	2.1×10^8	8×10^6
16	1.3×10^7	1×10^7
17	1.6×10^7	$>10^7$
18	8.6×10^4	4×10^4
19	$<10^3$	1×10^2
20	2.4×10^4	$<10^2$
21	3.1×10^6	5×10^6
22	5.5×10^3	1×10^3

*These are randomly selected samples taken on the same day.



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Committee on the Interplay
of Engineering with
Biology and Medicine

October 2, 1972

Mr. James T. Richards, Jr.
Chief, Technology Applications Division
Technology Utilization
NASA Headquarters
Code KT, Room 5021
Washington, D.C. 20546

Dear Jim:

This letter is submitted in response to your request for comments on two proposals involving transfer of aerospace technology to the development of medical equipment applicable to emergency medical care (EMC) systems. These proposals are. (1) Helicopter Patient Monitoring System submitted by Martin Marietta Corporation, Denver, Colorado, and (2) Portable, Lightweight Suitcase Containing Cardiac Monitoring Equipment (CARE) submitted by SCI, Houston, Texas.

Introduction

1. Martin Marietta

The Martin Marietta program for the development and evaluation of a prototype system for performing patient monitoring during emergency helicopter service proposes to use either (Option A) the existing SKYLAB Bio-instrumentation System OBS hardware to provide ECG, heart rate, and respiration rate plus a modified commercial blood pressure device based on SKYLAB technology, or (Option B) commercial hardware for monitoring ECG, heart rate and blood pressure (no respiration rate). Both options will include communications and hospital base display and recording equipment. Resuscitation equipment (e.g. oxygen, suction and defibrillator devices) on the helicopter will be identical to those used in a hospital intensive care (or coronary) unit. St. Luke's Hospital will participate in the field evaluation of a prototype system, providing the medical services and the helicopter that is now being used in conjunction with the

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Denver Police Department. The proposal also states that the results of the proposed program will provide data for supporting recommendations, justification and selection of equipment for existing and future emergency helicopter and ambulance service.

2. SCI

SCI proposes the design and development, utilizing applicable NASA technology, of a small, lightweight suitcase and of cardiac monitoring and resuscitation equipment to be installed therein; total weight of suitcase including equipment will be about 30 pounds. Following this development, SCI proposes that a field test be conducted utilizing the City of Houston's ambulance equipment and specially trained Emergency Medical Technicians (EMT's) under the supervision and with the support of the Harris County Medical Society located in Houston. The CARE suitcase will contain replaceable modules each performing a specific function, such as a 30-minute solid-state oxygen supply, ECG amplifier, a modified SKYLAB blood pressure system, a miniature defibrillator, communications system for both voice and ECG, an external pacemaker, an aspirator, a chart recorder, a pharmaceutical pack and a rechargeable battery/power supply.

General Comments

Both proposals have a common feature, lightweight cardiac monitoring equipment based on or adapted from NASA technology. Also, both proposals have a SKYLAB-oriented approach to a blood pressure system. The SCI proposal is more comprehensive since the CARE suitcase will also contain resuscitation devices. It is essential that the ability to measure vital signs be accompanied by techniques (manpower and/or conveniently available equipment) to overcome the patient's deficiencies implied by the physiological measurements.

In view of the predominance of ambulance usage over helicopter usage¹ for EMC, and juxtaposition of ambulance and helicopter systems, it appears that first priority between the two proposals should be given to

¹For emergency medical care, helicopter transport usage is only a few per cent of ambulance transport usage.

the SCI concept. Further, it is possible to meet both ambulance and helicopter needs by establishing a single environmental specification for both applications. Coordination and some consolidation in the design and development of the cardiac monitoring equipment are in order to avoid duplication of effort. For example, the Martin Marietta proposal does not specifically provide for the portability of the helicopter patient monitoring system. This feature is desirable, as in the SCICARE portable suitcase for ambulance systems, since initial treatment and stabilization of the patient may be some distance from the landing point of the helicopter. (Stabilization of the patient before transporting him to the hospital by either ambulance or helicopter is stressed by the City of Baltimore's Trauma Center.)

Additional, flexible features in the design of equipment under both proposals may be in order. We have talked to representatives of several communities who have stressed the desirability of having the ECG transmitter and the two-way voice transceiver inseparable units, so that the telemetry transmitter can be left on the patient from the pick-up point to the hospital, and so that the voice transceiver can be carried separately in non-cardiac situations.

Although each proposal has its origin in a different transport medium (helicopter or ambulance), both proposals have, or could be construed to have, the same ultimate objective--a universal set of physiological monitoring equipment either directly applicable² or readily adaptable, to both helicopter and ambulance environments. This orientation is recommended by the National Research Council, National Academy of Sciences, Division of Medical Sciences, as noted on page 23 of Public Health Service Publication No. 1071-C-3, Medical Requirements for Ambulance Design and Equipment. "Helicopters or aircraft used for the transportation of critically ill and injured patients should be designed and equipped to permit the same resuscitative and life-supporting measures and other emergency-care procedures as are described above for land ambulances."

²The Jacksonville, Florida, EMC system under Captain John Waters provides for EMT's and the appropriate ambulance-based emergency medical equipment to be transferred to a helicopter when required to complete the delivery of the patient to a hospital.

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Initial Recommendations:

In view of the foregoing comments, it is recommended that NASA initially undertake to coordinate the performance of the "first phase" of each proposal, namely, establish requirements, so that a single design and development effort for the common features of both proposals can then evolve.

Further consideration should be given to each user's primary (essential) or secondary (desirable or optional) need for the different types of physiological monitoring equipment. For example, discussion with representatives of the Office of Equipment Consultation, Health Facilities Planning and Construction Service, Health Services and Mental Health Administration, Public Health Service, Department of Health, Education and Welfare, has yielded the following guidelines for some of this equipment.

1. ECG telemetry is considered to be a primary need. However, temporary interruption of continuous ECG telemetry for voice transmission is to be avoided if at all possible.
2. Monitoring heart rate is considered a redundant measurement and therefore a secondary need.
3. Value of blood pressure measurement has not been fully explored and therefore considered a secondary need.
4. Respiration rate is considered to be of partial value, a secondary need, since what is really needed is the volume exchange of oxygen within the patient.

External Factors

A conversation on September 21, 1972, between Dr. Robert Donald, Chairman, Committee on Emergency Medical Services, Harris County Medical Society, Houston, and Mr. Abraham Leventhal of this Committee revealed that Dr. Donald has the blessing of the Mayor of Houston to proceed to interrogate several suppliers, including SCI, with regard to furnishing to Houston a 26-pound CARE-type suitcase. After this initial

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investigation, Dr. Donald's committee will recommend two or more suppliers for formal negotiations leading to a contract for the suitcase. This latest action by the Houston community, if carried to fruition, would place on industry the initial burden to develop the CARE-type suitcase.

A prior telephone survey by Mr. Leventhal of several potential suppliers of cardiac monitoring equipment similar to that proposed above confirms the appropriateness of the Houston approach. The potential availability of similar commercial hardware also relates to Option B of the Martin Marietta proposal, wherein commercial hardware (as is or modified) for monitoring ECG, heart rate and blood pressure is proposed as an alternate to SKYLAB-oriented hardware, Option A

Additional Alternate Recommendations

In view of Houston's latest action to proceed with the procurement of the CARE-type suitcase, it is recommended that NASA immediately establish liaison with Houston in order to coordinate their respective efforts. As an alternate, if NASA should elect to defer implementation of its action pending outcome of the Houston effort, NASA's initial contribution to Houston could be in the area of systems analysis (e g. assist in the preparation of system and hardware specifications) keeping in mind the desirability of a universal approach to physiological monitoring equipment for both helicopter and ambulance environments.

Summary

The comments in this letter have stressed the operational aspects of the physiological monitoring equipment discussed in both the Martin Marietta and SCI proposals and the desirability of a universal approach with respect to both helicopter³ and ambulance environment. This

³The suitability of the Bell Jet Ranger helicopter (Bell Model 206A) noted in the Martin Marietta proposal for ambulance service is confirmed on the basis of the MAST experience in that it meets minimum mission requirements. (See page 125 of Final Report by Stanford Research Institute, Evaluation of Operations and Marginal Costs of MAST Alternatives, Contract DAHC 19-71-C-0021, prepared for Director of Military Support Office, Chief of Staff of the Army, October 1971 [MAST - Military Assistance to Safety and Traffic]).

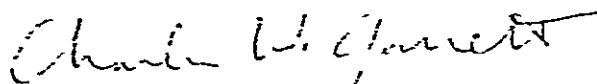
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orientation has been used with due consideration to (1) MSC's preparation of a detailed evaluation of the Martin Marietta proposal (re telephone conversation between Mr. Hoffler, MSC, and Mr. Leventhal) and (2) the general nature of the SCI proposal in comparison to the Martin Marietta proposal.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Charles W. Garrett".

Charles W. Garrett
Executive Secretary

CWG:ms
Enclosures

List of Potential Suppliers
for a CARE-type integrated package

1. Gould, Inc., Instrument Systems Division, Palo Alto, California
2. Physio-Control Corporation, Seattle, Washington
3. Biocom, Inc., Culver City, California
4. Pioneer Medical Systems, New Britain, Connecticut
5. SCI Systems, Inc., Houston, Texas

APPENDIX H

Major Field Trips Conducted by the
Subcommittee on Technology and Systems Transfer
and
National Academy of Engineering Staff

<u>DATE</u>	<u>SITE</u>
June 18, 1970	NASA-Ames Research Center
June 19, 1970	Jet Propulsion Laboratory
July 22, 1970	Baylor College of Medicine
July 23, 1970	NASA-Manned Spacecraft Center
July 28, 1970	Massachusetts General Hospital
August 6, 1970	Research Triangle Institute (BATeam)
August 7, 1970	Carolina Medical Systems (Industrial Interview)
August 25, 1970	NASA-Goddard Space Flight Center
September 10, 1970	NASA -Lewis Research Center
September 30, 1970	NASA-Manned Spacecraft Center
October 13, 1970	NASA-Marshall Space Flight Center
November 30, 1970	St. Elizabeth's Mental Hospital
December 28, 1970	Biomedical Computer Laboratory, Washington University, St. Louis, Mo.

<u>DATE</u>	<u>SITE</u>
January 5, 1971	NASA-Washington, Occupational Medicine Program
February 23, 1971	NASA-Goddard Space Flight Center
February 26, 1971	NASA-University of Virginia
March 5, 1971	NASA-Goddard Space Flight Center
May 12, 1971	Massachusetts General Hospital- Logan Airport/Remote Health Care TV System
May 13, 1971	Downstate Medical Center, Brooklyn, New York
June 18, 1971	Bowles Fluidics Corporation
June 24-25, 1971	NASA-Ames Research Center
June 25, 1971	Pacific Medical Center
September 27-October 1, 1971	Tufts Medical School, Boston
October 6 - 8, 1971	Downstate Medical Center, Brooklyn, AAMI Instrument Reliability Confer- ence, Boston, Emergency Care Research Institute, Philadelphia
November 1-3, 1971	Missouri Automated Physician's Assistant Program, other Regional Medical Program projects
November 11, 1971	Massachusetts General Hospital Boston (telemedicine project)
December 27-29, 1971	NASA-AEC Nuclear Rocket Develop- ment Site, Southern Nevada Memorial Hospital

DATESITE

December 30, 1971	Stanford Research Institute
January 3, 1972	University of Colorado Medical Center
January 4, 1972	Baylor University, Houston
February 14, 1972	Tennessee Valley Authority, Chattanooga
February 17, 1972	Massachusetts General Hospital- Veterans Administration Hospital (Bedford) Teleconsultation Link
February 23, 1972	Goddard Space Flight Center
February 23-24, 1972	Massachusetts General Hospital- Logan Airport Telemedicine Link; Cambridge Hospital and neighborhood clinics.
March 15, 1972	VA Hospital - Houston
April 6, 1972	Tennessee Valley Authority, Chattanooga
June 27, 1972	Cook County Hospital, Chicago, Ill.
August 25, 1972	Ohio Valley Health Services Founda- tion, Athens, Ohio
August 29, 1972	Harris County Medical Society, Houston, Texas
	NASA-MSC, Houston, Texas
September 5, 1972	University of Maryland Center for the Study of Trauma, Baltimore, Maryland
September 15-17, 1972	San Diego County EMS demonstration project, San Diego, California

<u>DATE</u>	<u>SITE</u>
September 18-19, 1972	Los Angeles City Fire Department ambulance service and Los Angeles County Hospital - University of Southern California, Department of Emergency Medicine
September 25-26, 1972	University of Minnesota, Minneapolis, Minnesota
September 27, 1972	Wisconsin State Emergency Services, Madison, Wisconsin
October 6, 1972	NASA-Manned Spacecraft Center
November 9, 1972	University of Maryland Trauma Center - Pulmonary Care
November 24, 1972	Nassau County, N. Y., Emergency Medical Services System
November 24, 1972	Virginia Beach, Virginia, Emergency Medical Services System
December 19-20, 1972	Jacksonville, Florida, Emergency Medical Services System
December 20-21, 1972	Miami, Florida, Emergency Medical Services System
March 29-30, 1973	Detroit, Michigan, Emergency Medical Services System
April 27, 1973	Wisconsin Emergency Medical Services State Planning Group, Madison, Wisconsin

APPENDIX I

Major Conferences Attended by the
Subcommittee on Technology and Systems Transfer
and
National Academy of Engineering Staff

<u>DATE</u>	<u>CONFERENCE</u>
June 1-2, 1970	NASA: GE-Patient Monitoring Study Program Plans
June 29-30, 1970	DOD: "New Generation of Military Hospitals" Program Review
July 6-10, 1970	Engineering Foundation: "Biomedical Engineering Optimization in the Health Sciences "
July 20-21, 1970	Federal Programs Consultants: "New Markets for Health Hardware-Software"
August 17-21, 1970	Engineering Foundation: "Introduction to Prosthetic and Sensory Aids"
September 21-22, 1970	HEW-RMP: "Instrumentation and Safety in the Cardiac Care Unit"
October 2, 1970	COBECC Workshop on Intensive Medical Care
October 8, 1970	NASA: GE-Patient Monitoring Study Advisory Group Session
October 21-22, 1970	PHS - "Telemedicine - Promise for 1980"
November 16-19, 1970	23rd Conference on Engineering in Medicine and Biology
November 20, 1970	NIH-NASA Symposium on Bioengineering
December 8-9, 1970	GE Patient Monitoring Study Final Advisory Group Session

<u>DATE</u>	<u>CONFERENCE</u>
January 19-20, 1971	DOD Helicopter Conference
March 18-20, 1971	Sixth AAMI Meeting
April 13-15, 1971	National Conference and Exposition on Electronics in Medicine
May 10-11, 1971	Goals and Problems in Intensive Care with Special Reference to the Surgical Patient/ American College of Surgeons and Division of Medical Sciences, National Academy of Sciences
May 24-26, 1971	AIAA Urban Technology Conference
August 2-4, 1971	Engineering Foundation Conference on Engineering in Medicine-Biotelemetry
August 30-Sept. 1, 1971	Instrument Society of America: Remote Health Care Systems
October 8, 1971	NAE, HSMHA, VA, NASA. Interagency Workshop on Remote Health Care
Oct. 31-Nov. 4, 1971	Alliance for Engineering in Medicine and Biology: 24th Annual Conference
November 1-2, 1971	NAE Fall Symposium: Application of Technology to Improve Productivity in the Service Sector of the National Economy
January 19-21, 1972	HSMHA: Technology and Health Care Systems in the 1980's
March 13-14, 1972	American Astronautical Society-Goddard Symposium: "Transfer of Space Technology to Community and Industrial Activities"
May 2-4, 1972	NIGMS: Automation in the Medical Laboratory Sciences Review Committee

<u>DATE</u>	<u>CONFERENCE</u>
August 24, 1972	NASA/GSFC: Seminar of GSFC Summer Institute in Biomedical Research
September 19-20, 1972	WESCON
September 21-22, 1972	Carnahan Conference on Sensory Aids
September 21-24, 1972	Emergency Medical Systems National Symposium
October 27-28, 1972	AAMI Tutorial on the Clinical Engineer in Today's Hospital
November 16-17, 1972	Conference on Advanced Systems for Health Care Delivery, Education and Information
November 21-22, 1972	AAS User/Developer Conference on Health Care Systems
March 24, 1973	AAMI Eighth Annual Meeting

FINAL REPORT
OF THE
PULMONARY CARE AD HOC GROUP
TO THE
SUBCOMMITTEE ON TECHNOLOGY & SYSTEMS TRANSFER

Committee on the Interplay of Engineering
with Biology and Medicine

NATIONAL ACADEMY OF ENGINEERING
Washington, D. C.
March 1973

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* * * * *

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FOREWORD

The National Academy of Engineering, in its role as an advisor to Congress and Federal agencies, has placed responsibility for studies of the engineering-medicine interface within its Committee on the Interplay of Engineering with Biology and Medicine. Under this committee is a Subcommittee on Technology and Systems Transfer which is concerned with the transfer of technology and expertise from within Federal agencies (e. g. NASA) to the public sector of health care delivery.

Three AD HOC GROUPS of engineering and medical experts were formed and asked to advise the Subcommittee in the following areas: Cardiovascular Care, Pulmonary Care and Remote Diagnosis and Treatment. Each group was presented with the following charge:

1. EVOLVE a statement of medical problems within the specialty of each GROUP as they pertain to the DELIVERY OF HEALTH CARE. Such a statement should rank problems in order of importance as based upon appropriate criteria which shall include (a) number of persons affected, (b) potential for solution within one to five years.
2. EVALUATE current projects and technology within NASA and other agencies which could have a high impact on the problems so delineated. The desired output is a judgment as to which NASA developments can contribute and are apparently ready for evaluation in a clinical setting. Those that hold potential but require further work (modified specifications, re-engineering to reduce cost, etc.) should be so specified to the greatest detail practical for such a GROUP to consider.

Recommendations are desired to a degree of specificity which could normally be anticipated as the routine of two or several meetings during the next few months.

The work outlined above will assist but cannot, by itself, provide substantive transfer. Because the Subcommittee is dedicated to acting as a catalyst in the PROCESS of technology transfer, it is hoped that members of the AD HOC GROUPS would also:

3. SUGGEST specific means by which the PROCESS of transfer can begin; for example, evaluation of items in specific clinics and hospitals, further development as required within specified laboratories, establishment of administrative relations between NASA and specific agencies in the health care sector.

The Ad Hoc Group on Pulmonary Care has concerned itself with the medical and engineering technology of respiratory intensive care. In choosing this very specific area of activity, the Group recognized that there are many other aspects of respiratory care which must be examined before any systematic nationwide program for such care can be contemplated. For example, the Group did not concern itself with epidemiologic factors of incidence and mortality, which clearly must be assessed before an overview of the economics of respiratory intensive care can be considered. The restriction of the Group's activities to the technological phases of the problem was a decision based both on the size and make-up of the membership, as well as the relatively short time allowed for this task.

The focus of this report is on the definition of medical problems encountered in a respiratory intensive care unit (RICU). These include the syndrome of acute respiratory failure, as well as the clinical information necessary, or at least helpful, for proper therapy. This summary is based both on the current state of the clinical arts and the approaches or techniques we feel are most likely to be useful in the reasonably near future.

From such a summary has emerged a definition of the technological problems which have not been solved but for which a strong likelihood of solution exists. The Group has also surveyed several such areas and recommendations are given for further NASA-supported research and development. Most promising in this regard is the mass spectrometer-flowmeter-computer system.

Finally, in the course of this study, various technological developments and miscellaneous bits of hardware have come to the Group's attention. It is not clear how, if at all, these devices will be useful in RICU's; however, they are intriguing, and workers in the field will want to be aware of them. Therefore, a brief listing with references appears as an appendix to this report.

One general conclusion has been reached as a result of this study. The most promising area of potential utilization of space and defense technology in pulmonary care appears to lie in diagnostic measurement and monitoring, rather than in therapeutics. Two facts support this conclusion. First, many industrial firms and many academic centers are heavily involved, and to a great extent successfully, in the development and use of ventilators and other equipment for respiratory care. Second, in therapeutic techniques the greatest problems are related to the requirements of well-trained workers, rather than the equipment they use. In contrast, the monitoring and measurement systems are relatively unsophisticated and prototypal; they have not successfully made the transition from the research laboratory to the bedside.

The Group therefore has concluded that the greatest portential for meaningful improvement in pulmonary care to which a NASA-developed technology could contribute lies in the field of diagnostic measurement and monitoring.

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RECOMMENDATIONS

RECOMMENDATION 1:

We recommend that NASA support and cooperate in programs of advanced development of an integrated system for continuous breath-by-breath analysis of respiratory flows and gas composition, as well as for blood gas measurement. Specifically this will involve study and development of new respiratory flow transducers, integrating circuitry and the mass spectrometer, which is proving useful for analysis in the gas and blood phases.

A. Respiratory Flow Meter (Section 2.1.2).

We recommend that further work be carried out on two NASA supported developments:

- (1) A fluidic low-speed air-speed indicator (Ref. 31).
- (2) A modulated frequency ultrasonic flow meter (Appendix K).

B. Mass Spectrometry. NASA has directed considerable effort to the development of mass spectrometry for the IMBLMS^{*} program and elsewhere, and therefore we recommend that this work be continued and be directed at clinical applications of blood and respiratory gas analysis. This program may include studies of both the magnetic sector and quadrupole types of mass spectrometer as well as necessary computational hardware and software, (Section 2.1.1 (c); Appendixes F, G, H). In the latter category, conversion of the spectrometer for ion counting and direct input into a digital computer should be evaluated.

^{*} Integrated Medical and Behavioral Laboratory Measurement System.

Such a program should develop design objectives in precision, frequency response, distortion, and stability, such as those suggested herein (Appendix G). Furthermore, economics dictate that such a device be multiplexed to serve several stations and that design of inlets and proper flow conditions be incorporated for such purpose (Section 2.1.1 (c)). Catheter tips should be designed for appropriate interface with such a system (Appendix H).

RECOMMENDATION 2:

We recommend that NASA cooperate in a program to investigate the pulmonary data-handling capabilities of IMBLMS for the purpose of developing an integrated computerized unit capable of broad application in clinical pulmonary care (Appendix J).

RECOMMENDATION 3:

We recommend that for purposes of research the following parameters be studied for a determination of (1) measurement technique, and (2) utility in acute respiratory care (Section 1.2.1): Total lung volume, lung diffusing capacity, lung water (improved technique desired), and regional lung volumes (gas trapping, air space closure, atelectasis).

RECOMMENDATION 4:

We recommend that the Subcommittee urge other appropriate Academy elements to further advise on transportation and communications systems for treatment of emergency respiratory patients and other emergency victims on a regional basis (Section 1.2.2).

RECOMMENDATION 5:

We recommend that NASA search their engineering and technology capabilities to help solve the problem of intracranial pressure (ICP) measurement. It is further recommended that prototype development and evaluation programs be established with knowledgeable medical and biomedical engineering groups (Section 1.6).

LIST OF SYMBOLS AND ABBREVIATIONS

General

- \bar{X} - Dash above any symbol indicates a mean value
- \dot{X} - Dot above any symbol indicates a time derivative
- B - Barometric
- C - Gas content in blood or compliance
- f - Respiratory frequency
- F - Fractional concentration of gas
- p - Gas pressure in general
- \dot{Q} - Volume flow of blood per unit time
- R - Respiratory exchange ratio ($\dot{V}_{CO_2}/\dot{V}_{O_2}$) or resistance
- V - Gas volume in general

Gas Phase

- A - Alveolar Gas
- D - Dead space gas
- E - Expired gas
- I - Inspired gas

Blood Phase

- a - Arterial
- c - Capillary

v	-	Venous
s	-	Shunt
t	-	Time or total

Specifics

C_aO_2	-	Arterial oxygen
C_cO_2	-	Pulmonary capillary oxygen content
C_vO_2	-	Mixed venous (pulmonary artery) oxygen
DC_L	-	Diffusing capacity of the lungs
ERV	-	Expiratory reserve volume
FEV	-	Forced expiratory volume
FRC	-	Functional residual capacity
Hgb	-	Hemoglobin
PA	-	Pulmonary artery
p_aCO_2	-	Arterial carbon dioxide partial pressure
p_aO_2	-	Arterial oxygen partial pressure
p_ACO_2	-	Alveolar carbon dioxide partial pressure
p_AO_2	-	Alveolar oxygen partial pressure
p_vO_2	-	Mixed venous (pulmonary artery) oxygen
\dot{Q}_s/\dot{Q}_t	-	Fraction of the cardiac output not participating in gas exchange
RQ	-	Respiratory Quotient
RV	-	Residual volume

S_aO_2	-	Arterial oxygen saturation of hemoglobin
S_vO_2	-	Mixed venous oxygen saturation of hemoglobin
SVC	-	Superior vena cava
Specifics (Cont.)		
TLC	-	Total lung capacity
\dot{V}_A	-	Alveolar ventilation
VC	-	Vital capacity
V_I	-	Inspired volume
V_E	-	Expired volume
\dot{V}_{CO_2}	-	CO_2 production per unit time
V_D	-	Dead space volume
V_D/V_T	-	Fraction of ventilation not taking part in gas exchange
\dot{V}_{O_2}	-	Oxygen consumption per unit time
V_T	-	Tidal volume

1. STATEMENT OF MAJOR PROBLEMS OF PULMONARY CARE

1.1 Introduction

This section describes five major activities of pulmonary care. They are (1) treatment of acute respiratory distress, failure, or insufficiency, (2) surgical monitoring, (3) ventilation-perfusion pathology studies, (4) pulmonary function testing, and (5) intracranial pressure measurement. In each case, medical technique is mentioned along with a review of desirable measurements. The major technological problems associated with these measurements are reviewed. Section 2 suggests the means by which some of those problems can be met through the joint application of engineering talent and sound medical judgment.

1.2 Respiratory Distress

The last decade has seen the evolution of modern respiratory intensive care from a short-term process of resuscitation to a sophisticated methodology in the treatment of severe pulmonary insufficiency. The direct application of known respiratory physiology to the care of the critically ill has resulted in marked salvage of life from respiratory failure caused by such diverse etiologies as thoracic trauma, poisoning, major surgery and neuro-muscular diseases. Additionally, the ability to support respiratory function post-operatively has assisted in the successful evolution of complex surgical therapy, including cardiovascular procedures.

Patients in a respiratory intensive care unit (RICU) are suffering from acute respiratory distress or disease.* Some will be chronic pulmonary cripples admitted

* See, for example, References 1, 2 and 3 for detailed discussions of the nature of acute respiratory failure.

to the RICU during a period of acute illness. Many will be admitted because of respiratory failure secondary to other problems such as severe trauma or surgery. In general, but not always, these are patients whose primary lesion is within the lung itself. Although patients suffering from polio or other paralytic diseases are less common than in previous years, respiratory impairment due to CNS depression is seen frequently. Typical causes are drug toxicity, head trauma and brain tumors. The management of these patients must not only include adequate monitoring of their CNS status⁽⁴⁾ but also the most skilled techniques of respiratory care. A serious danger with these patients, who are initially admitted with normal lungs, is that they can aspirate gastric contents, develop pneumonia, and deteriorate into the diseased lung category.

1.2.1 Respiratory Management via Cardio-pulmonary Monitoring. Acute respiratory failure implies an inability of the patient to spontaneously maintain viable blood gas and acid-base homeostasis in the face of insult to the respiratory system. Intervention must be based on accurate measurement of specific variables and knowledgeable interpretation of that data. In the application of technology to medicine, few areas have shown such clear and demonstrable success as in the treatment of acute respiratory failure. Central to this ability has been the application of measurements of cardiopulmonary function and the use of such knowledge to provide quantitative control of respiratory manipulation^(3, 5).

Monitoring capabilities, in general, are of two types. The first provides on-line, continuous observations and so marks precisely the change with time of a variable. They have been very useful in reducing mortality in coronary intensive care units, but their application has been limited in providing the information needed for an interventionist approach to respiratory failure. Physicians are forced to rely, for the most critical measurements, on the other form of monitoring: intermittent sampling, analysis, and integration. This is time consuming, often uncomfortable for the patient, and gives only infrequent results. Analysis of such data is required to provide the information needed for adjustment of ventilation and oxygenation. Information needed is as follows:

- (1) arterial oxygen tension
- (2) mixed venous (RV or PA) oxygen tension
- (3) arterial and mixed venous oxygen content
- (4) pH
- (5) oxygen consumption
- (6) cardiac output
- (7) inspired oxygen tension
- (8) mixed expired CO_2 tension and end tidal CO_2 tension
- (9) temperature
- (10) tidal volume
- (11) respiratory rate
- (12) peak airway pressure

From these data, a number of derived variables may be determined which are mandatory for proper management of a patient in respiratory failure. They include the well-known parameters of cardiac output, oxygen consumption, and carbon dioxide production. Calculations appear in Appendix A.

Respiratory management, in addition, requires basic qualitative data:

- (1) Is there spontaneous respiratory activity?
- (2) Is the activity effective--i. e., if the patient is on a respirator, is he controlling it?
- (3) If he is not driving the respirator, is his activity synchronous with its control mode?

- (4) If not synchronous, is his activity interfering with the effectiveness of ventilation or is it imposing an unacceptable metabolic load on him?

Ventilatory mechanics involve a separate list of primary and derived properties, both passive and active.

Passive properties include total compliance (tidal volume/static end inspiratory pressure, assuming no positive end inspiratory pressure). Ideally, separate components of lung and chest wall compliance should be available. This would require measurement of pleural pressure by intra-esophageal balloon. Anatomic dead space; physiologic dead space, and the ratio of dead space volume to tidal volume are desired.

Resistances of the airway, lung, and chest wall also are in this category.

An additional measurement that would be useful would be total lung volume. This would require either plethysmography or indirect measurement by gas dilution. Further development studies are needed to make most of these passive properties available as bedside measurements.

Active properties are inspiratory force (the maximum negative pressure the patient can generate by spontaneous activity), ventilatory volumes (tidal volume, vital capacity, expired minute ventilation) and respiratory rate.

Vigorous maneuvers such as maximum breathing capacity, forced expiratory volume (FEV), etc. have not been used with patients in failure who lack the ability or strength to cooperate. However, passive measures of FEV with animals have been done and are useful. This approach might bear further exploration in patients.

Several additional types of pulmonary function determination could possibly be advanced. However, it is important to recognize that at present these fall into the research category. In some cases the methods of measurements are not adequate (for routine bedside use) or even developed. More important, even when the validity of the determination has been proved, it is not always clear what place, if any, the measure has in acute respiratory care. Included in this category are lung diffusing capacity, lung water (currently done by double indicator dilution), regional lung volumes, gas trapping, air space closure, and atelectasis.

In view of the rapidity of change of such critical variables as cardiac output, venous admixture in arterial blood, physiologic dead space and compliance, such intermittent measurements are useful but inadequate for observation and decision making in the critically ill. This report suggests the adaptation of recent technological developments and computer capabilities to provide rapid and semi-continuous measurement of changing derangements in cardiopulmonary function. Such an informational flow would allow rapid alteration of ventilator and oxygenation therapy before changes in blood gas homeostasis become life-threatening.

The development of rapid and reliable continuous monitoring would be a quantum step forward in both the management of acute respiratory failure and in the understanding of the evolution of disease process. In addition to the need for accurate diagnostic data, on-line monitoring could lead eventually to automated aspects of a patient's management, such as the control of a ventilator. The technical problems are formidable but soluble if an interdisciplinary team of physiologists, clinicians and biomedical engineers address themselves intensively to the adaptations of known technology to the solution of this problem in a clinical setting.

1.2.2 Emergency Respiratory Care in Outlying Regions.

Frequently, patients in respiratory failure are admitted to outlying or rural hospitals which lack adequate pulmonary care facilities. Such patients may be inadequately managed and

transferred too late to a major respiratory care center. The Ad Hoc Group agrees that improved transportation and communication systems need to be established within the larger framework of an overall regional emergency care system.

In addition, techniques are needed for providing emergency respiratory care by the relatively unskilled worker. The issue can be framed as follows. Given a patient in acute respiratory failure for which the etiology may be varied and not always known, what are the minimum essential measures that can be applied outside of a respiratory care center?

1.2.2 (a) Exercise of medical judgment. Is respiratory support needed? If it is not needed, may it do harm? Chronic pulmonary disease patients can be harmed by improper use of ventilators in several ways, for example, by a too rapid elimination of CO₂.

1.2.2 (b) Airway management. Key to the application of a respirator in an acutely ill patient is the management of the airway. A mask or a voluntarily held mouthpiece is not adequate for prolonged support and the airway must be kept open by direct tracheal connection. Of the three approaches (oral intubation with an endotracheal tube, nasal endotracheal intubation, and tracheostomy), oral intubation appears to offer the least hazard in unskilled hands. However, improperly performed intubation can be permanently damaging to the larynx and other parts of the airway and in general it has not been possible to train paramedical personnel, or physicians performing it only occasionally, to make the procedure a safe one. Life-threatening emergencies may be caused during intubation when asphyxia, acidosis, hypotension, sympathetic activity and powerful parasympathetic reflex activity may exist concurrently.

Up to the present time intubation is learned by intubating cadavers and anesthetized patients. Clearly, this can never become widespread enough to develop a large corps of people competent to do it. The development of mannequins, similar to those used in other aspects of resuscitation, may prove useful in this regard.

If one were to examine the difficulties of intubation, it might be possible to see several areas for improvement such as tube design and materials (for example, how to secure the tube during transport), laryngoscope design, etc., however, at the present the personnel appear to be more important than the equipment.

1.2.2 (c) Medication. Also relating to the technique of airway management, medications are often used. Except for the unconscious patient, in general it will be necessary to use medication in the placement and maintenance of the endotracheal tube. Topical anesthetics are not without hazard nor are the paralytic drugs. Again, this appears to be an area in which the needs for medical training and judgment cannot be reduced by new hardware.

1.2.2 (d) Ventilation. Assuming that intubation could be performed safely and that the patient could thereby be made ready to receive respiratory support, the methods of ventilating can be considered. As long as the proposed period of support by this ventilator is kept to less than 48 hours, it seems clear that oxygen toxicity hazards are not great and a gas mixture may be selected which contains 80 - 90 percent oxygen. If the patient is being adequately oxygenated (we assume blood gas data are not available during this period and that we are relying on clinical signs such as cyanosis), the major hazard then devolves to CO₂ elimination. One possible method which might assure proper CO₂ elimination, without blood gas data, would be to over-ventilate using an inspired CO₂ mixture to prevent the elimination of too much CO₂ from the blood. This method is widely used by police and fire departments. Usually, the CO₂ concentration is in the range of three to five percent. If this approach were to be pursued, it would certainly have to be investigated extensively. Some data are available for the effects on normal subjects of breathing three to five percent CO₂, but not for patients in pulmonary failure--especially those with chronic or acute CO₂ retention.

A further area for research would be on the effects of over-ventilation on a patient in shock. At extremely high ventilatory rates and volumes the increased mean

intrathoracic pressure caused by the respirator can impair circulation.

The foregoing, especially the concept of using a pre-selected gas mixture containing a fixed percentage of CO_2 , suggests that a set of tables or a nomogram be prepared for the ventilation of patients in this way. The new nomogram would be analogous to that prepared by Radford,^(6, 7) but would be based on the inspired pO_2 and pCO_2 .

At present, the best respirator for this application would be a time-cycled volume-controlled machine in which the peak inspiratory pressure could be set by the operator and the tidal volume monitored. Assisted ventilation, unless extremely close monitoring of the blood gases is available, should not be used in the acute phases of respiratory failure, and therefore no trigger or assist should be incorporated into this ventilator. There are several ventilators commercially available which come close to these requirements or which could be modified to meet them.

In summary, the problems of reliable management of acute respiratory failure patients who are in remotely located regions are more problems of personnel and technique than of technology.

Given the needs for better trained personnel in the outlying areas, one is still faced with many questions relating to the equipment or, more properly, to the relationship of the worker to his equipment. In an emergency, is a fool-proof respirator a good idea? If available, would it be used? Would it be used correctly; that is, for not more than twenty-four to forty-eight hours? Would hospitals transport or refer patients to centers in time? Would the doctors? If so, how? In other words, what is the likelihood of changing the pattern of pulmonary care by such technological changes in two to five years?

It is the feeling of this group that a technological undertaking such as the development of a new respirator should be considered with great care and well may not be worth pursuing, except in a much larger context of major changes in

health care delivery patterns in this country.

1.3 Surgical Monitoring

Much of the original information which demonstrated that there were unexpected and clinically significant derangements in blood gas homeostasis came about through the use of polarographic analysis of samples taken during the course of major operative procedures. It became apparent that many complex interactions occurred which could result in hypercarbia and/or hypoxemia. Experience gained during medical operations led to the important observation that normo-carbic hypoxemia was common and resulted from alterations in ventilatory pattern due to anesthesia and surgery. Investigations were carried into the recovery room and it soon was realized that hypoxemia was a major, and usually unrecognized, cause of death in the immediate post-operative period. Thus, it became apparent that blood gas monitoring should become a common feature in the care of many patients undergoing major surgery. Blood gases are now considered as essential in monitoring the vital functions of a patient during surgical operation as blood pressure or the electrocardiogram.

In major hospitals, blood gas determinations are carried out in specialized satellite laboratories adjacent to both the operating room and the intensive care unit. Of particular importance has been the intraoperative and immediate post-operative management of patients undergoing heart surgery with cardiopulmonary bypass. Without the ability to monitor (even intermittently) arterial oxygen, carbon dioxide and pH, such radical intervention would be even more difficult than it already is. A significant reduction in morbidity and mortality has generally been ascribed to both the information derived from blood gas analysis and to the increase in understanding of vital processes which the physician has acquired through the availability of these methods.

The current state-of-the-art in blood gas analysis is still rather primitive in most hospitals. Samples must be removed from a peripheral artery and analyzed separately by polarographic and electrometric techniques. Although a great deal of information can be derived from such intermittent sampling, it has several major drawbacks. A skilled technician is required to obtain reliable data. Inaccurate results are not uncommon. Intermittent sampling increases the risk of infection. Most seriously, however, the intermittency of the information gathered precludes the acquisition of much scientifically and clinically useful information. Slow, remote analysis makes correlation of many of the variables measured impossible. As an example, there are clear relationships between cardiac output, relative venous admixture and alterations in dead space to tidal volume ratios. The manner in which they affect one another has never been properly investigated, simply because rapid on-line measurement and data analysis have not been possible. The use, therefore, of mass spectrometer technology and a suitable small dedicated computer could provide a quantum jump in our understanding of intraoperative events and our ability to care for those undergoing major surgery in an optimal way.

1.4 Ventilation-Perfusion Pathology Studies

Our current understanding of the clinical occurrences which cause alterations in blood gas tensions are a great deal more sophisticated than they were as few as five years ago. Nevertheless, our concepts are still extremely simplistic. The gap between the degree of understanding of the skilled respiratory physiologist and the intensivist in the hospital setting is a large one. Even the more sophisticated clinicians still tend to think of alveolar-capillary relationships in the simplistic terms of pulmonary capillary blood perfusing collapsed alveoli and so ventilating areas without blood supply. Although these are useful concepts, they are grievous oversimplifications of the true state of events, which is almost invariably a relative maldistribution of ventilation and perfusion. Accurate measurement of such alterations is technically exceedingly difficult. Because of this, clinicians have seldom

come to grips with true \dot{V}_A/\dot{Q} physiology. The ability of the mass spectrometer to measure not only oxygen and carbon dioxide, but also the partial pressure of nitrogen and other inert gases in blood should provide the requisite technical capability to give physicians a more accurate and realistic understanding of intrapulmonary pathology at a level of intellectual and technical sophistication hitherto available only in the research laboratory.

1.5 Pulmonary Function Testing

Pulmonary function tests have become an important element in the growing number of automated health testing facilities for early detection of respiratory disease. The possibility exists that with the exception of pulmonary compliance, all important parameters could be measured with only two instruments: the mass spectrometer and an accurate flow meter. A dedicated computer would simplify calculations and provide on-line data. Fundamental equations appear in Appendix B.

1.6 Measurement of Intracranial Pressure

The problem of continuous, accurate, and reliable recording of intracranial pressure (ICP) for diagnostic and management purposes in patients following head trauma, brain operation, ischemic or anoxic insults, intracranial cerebral hemorrhage and other cerebral causes of coma is important to solve. Currently the problem is either avoided or else occasionally unnecessary surgical interventions are instituted to correct suspected elevated pressure when operating may have been unnecessary.

Several criteria are important in the development of the best possible ICP device. Specifically measurements should.

- (1) Be made, if possible, extradurally.
- (2) Involve an acceptably low risk of infection and as little discomfort to the patient as possible.

- (3) Be implantable and preferably wireless.
- (4) Have small physical size and lowest possible physical mass.
- (5) Be able to be calibrated and zero-shifted from outside the body.
- (6) Be stable so that frequent calibration is unnecessary, thus yielding instantaneous and continuous information.
- (7) Have minimal temperature sensitivity.
- (8) Be impervious to the surrounding environmental conditions within the head.
- (9) Be useable for an extended period of time, i. e., at least seven days and preferably for as long as thirty days, during which time measurement can be repeatedly performed.
- (10) Be sensitive to pressure changes of 1 mm Hg or less and sensitive to pressure relative to atmosphere.
- (11) Not require exorbitantly expensive equipment.

The history of intracranial pressure recordings goes back many years, but the first major landmark attended the publication of Nils Lundberg's monograph, "Continuous Recording and Control of Ventricular Fluid Pressure in Neurosurgical Practice," published in 1960. (8) Dr. Lundberg reported on some one hundred thirty patients, most of whom were pre-operative brain tumor patients in whom he had recorded pressure from a cannula in one of the lateral ventricles of the brain. Investigations by T. W. Langfitt, et al. at the University of Pennsylvania paralleled these investigations. (9,10) Since 1960 many investigators have searched for a solid state device to do the same thing. The disadvantage of intra-ventricular recording techniques are:

(1) It may be difficult to tap the ventricle in patients with small ventricles due to brain swelling, (2) The cannula may obstruct and can be unobstructed only by injecting saline into the ventricles, a potentially dangerous maneuver for several reasons; (3) An inside-outside fluid connection tends to increase the risk of infection, and (4) It is necessary to insert the cannula through the brain (although this is a common practice in other circumstances, it should be avoided whenever possible). A major advantage of the intraventricular cannula is that fluid can be withdrawn from large ventricles, a most effective means of rapidly reducing intracranial pressure and for examination (e. g., chemical analysis) in severely ill patients.

Measurements from the extradural space introduce the potential of artifact. If the dura is firmly attached to the surrounding skull, and if blood and other fluid oozes into the space containing the transducer during the course of the recording, artifactually high pressure may be recorded.^(9,10) The incidence of infection in Lundberg's series and in the University of Pennsylvania unpublished observations on more than one hundred patients is one to three percent. It is suspected that the infection rate with an extradural or subdural transducer will be much lower than that, if not virtually nonexistent.

A wireless transducer is probably not necessary in monitoring acutely ill patients, it requires an operation to implant the device and another to take it out. Moreover, implantation makes calibration less feasible. What is needed is an instrument that can be inserted at the patient's bedside through a stab wound in the scalp and a twist drill hole through the skull.

Although several Statham Corporation prototypes have been tested, none worked adequately and the Statham Corporation is apparently uninterested in correcting the deficiencies. Recently another transducer, "Sensotec," was manufactured by a division of the Comtel Corporation, Columbus, Ohio. So far there are four patients in whom ICP has been recorded simultaneously with a cannula in the lateral ventricle and with the Sensotec inserted through the same trephine hole into the subdural space. The Sensotec drifts, but so do the transducers to which

the intraventricular cannula is attached. The Sensotec is six mm in diameter and has a thickness of two mm. Thus it is small enough, but it cannot be calibrated in vivo, in contrast to the ventricular cannula, and this is a major objection. Temperature sensitivity is important when there are major temperature swings such as in the brain of those cooled by extra-corporeal circulation. Temperature may not be a major problem within the temperature ranges of many cases encountered clinically. (11)

There is a place for an implantable, wireless device such as the one developed by Atkinson, Shurtleff, and Foltz. (12) Their instrument was designed specifically to measure intracranial pressure in hydrocephalic infants for weeks or months. This illustrates the point that we should be thinking in terms of "highly" reliable transducers if monitoring is to be carried on for months.

A comparable continuous telemetric monitoring ICP device has been described by M. Brock, et al. (13) The device fits into a sixteen mm burrhole. It contains a capacitance pressure sensor, a transmitter, and battery within a silastic coated container. A pressure equalizer tube maintains reference to ambient air, thus the device is of the differential type. Extensive trials have not been conducted.

Dr. B. Watson at the Department of Medical Electronics, St. Bartholomew's Hospital, (London), has worked with an extradural sensor which involves introducing a thin fluid-filled tube between the dura and the skull, connected with a pressure sensitive radio pill mounted on the surface of the skull. The transmitter can then be covered with dressings which do not have to be disturbed to make a measurement. The device is, however, not implantable and because it is mounted externally to the skull, one does not have to strive for the absolute minimum of size or mass.

With the present state-of-the-art it may not be possible to construct a totally implantable device which can be relied upon to hold its zero and calibration for any length of time. For acute measurements, arrangements should be made for a

communication with the atmosphere for the purpose of providing a reference pressure, even if the signal is transmitted by telemetry. To get over the problem of local mechanical forces, a transducer system is recommended. Built into a plastic button, this could be sealed into a burr hole in the skull in which the space between the transducer diaphragm and the dura would be either filled with a suitable liquid or even with a jelly to discourage the formation of fibrin clots and invasion by cells.

One approach, recently introduced in connection with a catheter tip blood pressure transducer, eliminates the need to check both zero and slope. It has possible application to an intracranial pressure readings, if some connection through the scalp were admissible. In this approach, a rigid, hollow metallic transducer body is fixed onto the end of a plastic catheter and cuts are made into the transducer in such a way as to produce a flexible tongue which only remains connected to the transducer body by one of its short sides (rather like a reed in a mouth-organ). Fixed to the inside of the flexible tongue are one or more silicon strain gauges, their connections being led away via the plastic tube. The whole transducer is covered by a thin rubber membrane which is joined in an air-tight seal to the plastic catheter. The end of the catheter is normally open to the atmosphere. When the device is acting as a pressure transducer, the tongue is deflected and the movement is detected by means of the strain gauges. To check the zero a positive pressure is applied to the open end of the catheter which is slightly larger than the pressure applied to the transducer. This inflates the rubber membrane just clear of the transducer body so effectively abolishing the pressure difference across the flexible tongue, zero can thus be checked. To check the slope, a known negative pressure is applied to the open end of the catheter which adds to the pressure applied to the transducer and produces an output increment indicative of the slope. This system is presumably the subject of a patent which is now held by S. E. Engineering Limited of Feltham, Middlesex (England). It does appear to overcome most of the disadvantages associated with a remote transducer.

A further system of interest for possible correlation with ICP measurements is electrical impedance cephalography (EIC). If care is taken to work with good equipment using guarded electrodes of reasonably large size and either a two-, three-, or four-terminal system, interpretable and reproducible records are obtained. With appropriate signal averaging, there is apparently a characteristic change in the EIC with increased ICP which includes an increase in the amplitude of the wave and a concavity toward the base line of the descending portion of the wave as well as an increase in the ECG to EIC initiation time.⁽¹³⁾ This direct and noninvasive assessment of ICP should be explored further.

There is now general agreement that the ICP technique is a valuable adjunct in the management of neurosurgical and other patients and no longer just a research tool. In fact, ICP has become one of the vital signs in head-injured and postoperative craniotomy patients, as well as in a variety of other conditions, and has the same significance for the patient as measurements of blood pressure, pulse, and respiration. The development of a stable device that can withstand a fair amount of punishment would be a tremendous help to critical care medicine.⁽¹⁴⁻¹⁵⁾

2. STATEMENT OF PROPOSED APPLICATIONS OF TECHNOLOGY

Two technological problems are common to four of the activities described above. One is a problem of instrumentation; the other is one of system integration and computation. Each is discussed below.

2.1 Instrumentation

Two distinct functions of pulmonary instrumentation are (1) blood and respiratory gas analysis, and (2) respiratory flow measurements.

2.1.1 Gas Analysis by Mass Spectrometer. Blood and respiratory gas analysis can be improved through the development of a specifically designed mass spectrometer although the former is highly dependent on membrane technology. It is feasible to provide modules for respiratory, blood, and tissue gas analysis, all using the same analyzer. It is also feasible to provide one mass spectrometer to serve the monitoring needs of a multiple-bed ward. Designs have been proposed (particularly in the gas mode) which would allow sampling at distances up to one hundred feet from the analyzer, via suitable inlet pumping and switching systems. Accuracy and stability of the mass spectrometer are reported to be suitable for continuous as well as intermittent applications.

(a) State-of-the-Art. A description of the state-of-the-art in mass spectrometry is found in Appendix C. Mass spectrometers have been used in respiratory monitoring since the mid-fifties. (25, 26) Recent development of mass spectrometry technology allows the continuous measurement of gas tensions in blood, either in vivo or in vitro. This capability allows the transition from infrequent measurements which are difficult to correlate with other events, up to and including a virtually continuous recording.

Arterial oxygen and carbon dioxide tensions can be utilized in the computer solution of a number of important equations, e. g., venous admixture, dead space to tidal volume ratios, alveolar to arterial oxygen differences, and cardiac output. Intermittent measurement of hemoglobin, pH and

temperature can be made and entered into a computer program. Arterial and venous oxygen content measurement can be calculated if the known constants for the oxygen-carrying capacity of hemoglobin and the solubility of oxygen in plasma are carried by the computer.

Continuous sampling of blood is possible via a silastic-tipped catheter. Analysis can be made of pO_2 , pN_2 , pCO_2 , and partial pressures of other gases simultaneously, with a response time of less than thirty seconds. Intermittent sampling from sterile syringes is a more conventional technique, and has the advantage that many patients may be served by the same equipment and also that multiple sampling sites (arterial and venous) for the same patient may be used.

b. NASA Developments in Mass Spectrometers. NASA has sponsored a detailed comparison of mass spectrometer designs for an atmospheric sensor system.⁽²⁷⁾ They have amplified this initial work with a proposal for a mass spectrometer system for pulmonary function studies aboard Skylab. Some criteria are sufficiently close to respiratory ICU, surgical monitoring wards, etc., that they can be considered here. However, whereas the original study emphasized comparisons of instrument size and weight, civilian medical use would require greater emphasis on fast response time for respiratory gas calculations, precision for blood gas calculations, and cost.

Eight mass analyzers were reviewed by NASA. Two designs were selected as most useful for flight specifications and were subjected to a detailed analysis and comparison. These were the single focusing magnetic sector analyzer and the quadrupole mass filter. The results of the NASA study slightly favored the magnetic sector analyzer. A summary of results is found in Appendix D. Appendix D also contains a summary of subsequent design analyses. Five space flight rated instruments of the magnetic sector design were fabricated and delivered based on the NASA study.⁽²⁸⁾ Two of the instruments were evaluated for respiratory gases.⁽²⁹⁾ Two upgraded versions for respiratory analysis have been delivered to NASA for testing.⁽³⁰⁾ Specifications appear in Appendix E. Results from early tests with these instruments are not yet available.

A prototype commercial version of the magnetic sector device has been delivered to Latter Day Saints Hospital, Salt Lake City, for testing. See Appendix C.

Appendix F contains more information on the quadrupole type which was not chosen by NASA.

For application to medical care at this time and for the uses detailed below, a magnetic sector device appears slightly preferable, although the distinction has lessened recently. The specific device chosen by NASA appears to qualify as an appropriate device for clinical implementation. Less sophisticated electronics have yielded a more stable, reliable instrument which can simultaneously monitor up to seven channels. Current quadrupole devices in clinical use such as the one at the University of Minnesota may encounter problems in long-term stability. Recalibration has reportedly been required every eight to twelve hours. However, such systems will undoubtedly be improved and further developmental work should be supported as well.

(c) Recommendations for Further Work on the NASA Instrument. Prolonged respiratory flow and concentration monitoring, coupled with an ability to measure blood gases in real time, may lead to a significant improvement in patient care in the respiratory ICU. It may also improve the monitoring of patients under anesthesia and improve the assay of patients in the pulmonary function laboratory.

In order to obtain this flexibility, equipment must be assembled which includes a respiratory flowmeter, a temperature stable respiratory pressure transducer to measure maximum inspired air and dynamic compliance, a mass spectrometer gas analyzer and a computer with appropriate software for on-line data calculation.

To optimize the utility of mass spectrometry in clinical medicine and biological research, it is imperative that it be possible to measure gas tensions in both the blood and respiratory gas phase. To date, NASA has addressed itself only to the use of the mass spectrometer in measurement of the gas phase. The development of technology which will allow in

vivo sampling of gases in the blood phase is essential. Provision for nurse or technician operated pO_2 , pCO_2 , etc. blood gas analysis should be provided as one part of the inlet system. A holding chamber can be provided for blood to which the mass spectrometer converts from respiratory analysis. Blood would be pumped to the membrane-analysis section. After analysis, means for automatic flushing and cleansing would be required.

Reliability is essential for its application to intensive care units. Also it must be emphasized that it cannot be known with certainty which measurements will prove best for medical care. Therefore, a flexible device which can meet a variety of requirements is important as well.

Specific requirements for instrument precision, frequency response, distortion, and stability are detailed in Appendix G. Problems related to catheter tips are outlined and design objectives specified in Appendix H.

The mass spectrometer should not be dedicated to one patient. Ward usage patterns and economics require multiplexing the instrument to several patients in a respiratory ICU or surgical setting. This is a non-trivial problem requiring a programmable sampling valve for use in the 1-100 torr range. Sampling lines up to 100 feet must be considered. A three-stage, rather than two-stage, inlet system may be required, in order to remove effects due to water vapor⁽³¹⁾ and also to accurately control the sample lag time. Distortion of step changes in concentration during travel down the very long inlet lines may require development of a transfer function to correct the instrument response. The equations governing flow in the transition region between viscous-laminar and molecular flow suggest that an isothermal condition is desirable during this phase of sampling. Trade-offs between viscous flow and sampling line volume must be made in order to optimize sampling time versus distortion performance. To the Group's knowledge, none of this work has been performed by NASA or anyone else.

The Group recommends that such a development program should aim to decrease the cost of a commercial version of the mass spectrometer to a figure approaching \$5,000, exclusive of a multiple inlet system, but including both blood and respiratory gas sampling modes. The physical size of the

instrument should be as small as possible. Only by such investment of development support will it be assured that the instrument will have impact for a large segment of the medical community.

Much of the above work can be accomplished by NASA with appropriate biomedical and engineering consultation. For the clinical trials, protocols for assessment of the following crucial questions must be generated and committed clinical personnel identified who can conduct this work.

1. Does the computer-based respiratory patient monitoring system measurably assist in improving patient care and reducing mortality and morbidity?
2. Does the computer-based surgical monitoring system measurably assist in improving patient care and reducing mortality and morbidity?
3. Does the computer-based pulmonary function testing system measurably assist in improving patient care and reducing mortality and morbidity?
4. What is the cost-effectiveness posture of this system in each of its three envisioned settings?

This program will require substantial financial support, possibly as much as \$200,000 for several years. A staff of technicians will be required to maintain the equipment. Detailed protocols for rigid statistical evaluation of its effectiveness will need to be designed. Finally, a long term commitment from a clinical center, with an adequate RICU patient flow for intimate association and interaction must be forthcoming.

2.1.1. Respiratory Flow Measurement. Measurement of respiratory flow is the second major problem in pulmonary care. Flowmeters provide information on the performance of respiratory mechanics. Coupled with a mass spectrometer, it enhances the possibilities for information on gas exchange.

There are several flowmeters on the market which perform satisfactorily in the hands of skilled physiologists and in the controlled conditions of a laboratory. However, for routine use with patients under intensive care, additional design constraints arise from this quite different environment. The flowmeter must be easily cleaned in a way which does not affect delicate calibration. The device must not be fragile, for it undoubtedly will be dropped or will impact with other objects. And its design cannot present a hazard when it is exposed to a potentially explosive anesthetic gas.

Of those respiratory flowmeters in current laboratory use which provide sufficient accuracy, all fail in one or more of these respects. The effect of this failure has been to remove such measurements from the realm of the routine and thus to severely restrict the number of patients whose care could benefit from their ready access.

NASA, for its Integrated Medical and Behavioral Laboratory Measurement System (IMBLMS), surveyed available flowmeters and integrating circuitry. This survey resulted in the decision to fly a spirometer with the flowmeters. It is significant that despite other available devices such a standard tool was still deemed necessary. Flowmeters surveyed included laminar flowmeters (Fleisch or Silverman), turbine, hot wire, and inert gas dilution (Beckman). In all cases they found that the integrated flow is neither as reliable nor as accurate as the volume trapped by a spirometer.

Several difficulties arise in the attempt to design an instrument to meet this need. A problem yet to be completely solved is the proper phasing of a flowmeter signal with gas composition as determined by a mass spectrometer. One approach is to pass the signal from a conventional pneumotachograph flowmeter through a device which delays and distorts it so that it is in phase with the spectrometer.

A second problem is the required compensation for varying gas composition and temperature. The oxygen concentration differs in the inspired and expired air by approximately four percent, as does the CO_2 level. The patient may be breathing anywhere from twenty-one percent to one hundred percent

oxygen. The expired air generally has one hundred percent humidity at body temperature; frequently there are entrained moisture particles. Therefore, either the flowmeter must have built-in compensation for variation in gas composition and humidity or it must at least be possible to demonstrate that, with an adequate gas analysis system, such compensation can be made by calculation. A related fluid development is that of a device for the measurement of airway humidity.⁽³⁵⁾

These and other considerations are incorporated in a suggested set of engineering specifications for a respiratory flowmeter. These appear in Appendix K.

Two recent developments are encouraging. Both underwent initial development with NASA support. The first is a fluidic-low speed air-speed indicator.^(32,33,34) This approach uses a secondary air jet which is modulated by the main stream. Air velocity detection ranges from velocities of 0.33 to 99 feet/sec in the designs tested so far. Originally developed for use in V/STOL aircraft, it is now being considered for use as a coal mine ventilation monitor.

This air speed sensor can probably be adapted to volume flow since air speed is related to volume flow. This is true because the size of the sensor orifice remains constant. A question of boundary layer effect on the performance may be valid, however, the boundary layer is expected to be small. A proper calibration of the sensor will correct this difficulty. Temperature may also be a factor but this again is predictable. The Group recommends that this project be pursued.

Ultrasonic flowmeters, such as Doppler-effect devices, are in use for blood flow measurement, and are currently being studied for measuring respiratory gases. Statham Instruments has developed and demonstrated such a device. Recently a NASA development at the Electronics Research Center has resulted in an extremely promising ultrasonic flowmeter which appears to offer at least as great accuracy for lower cost. This is the Modulated Frequency Velocimeter described with the Statham device in Appendix L.

Each of these two flow meter designs, the fluidic air speed and the ultrasonic, has its own advantages. While the characteristics of fluidic devices are less well understood than those of ultrasonic instrumentation, the devices themselves are easier to fabricate, and are extremely simple in construction. They may also prove to be mechanically more durable.

It is not unlikely that in different applications each might have an advantage. Therefore it is recommended that both developments be extended to medical application.

2.2 System Integration and Computation

Although advanced development of a broad array of technical instruments may have a major impact on the treatment of pulmonary patients, the value of data thus collected will be severely reduced if it is not accompanied by what is commonly termed system integration and computational procedure.

For patient management it is important to obtain results rapidly. This and the sharp variations in gas tensions and flow during the breathing cycle make it clear that real time computations by digital or analog computer are required. A considerable software effort is necessary to successfully carry this out. Computers and mass spectrometers are expensive devices. Cost per patient-day must be given consideration, and it follows that a multiplexing system must be constructed to allow multiple-bed service. Spectrometer inlet design, pneumatic switching to allow multiple-bed sampling, simple lag and distortion in transit to the spectrometer and a multiplicity of error corrections in various pulmonary computations must then be faced (see Appendix I).

These considerations are lumped under system integration. Recent work has suggested that the problems are identifiable and solvable for the clinical setting.⁽³⁶⁾

NASA's activity in this regard is exemplified by the IMBLMS (see Ref. 37 and Appendix J for a summary).

To summarize, the Pulmonary Care Ad Hoc Group urges that the Subcommittee support programs to improve and integrate available but disparate subsystems into a functional unit which will provide detailed and sophisticated cardio-pulmonary information at a high data flow rate.

APPENDIX A

Derived Variables of Cardiopulmonary Function

1. Degree of venous admixture or shunt-like effect due to the functional bypassing of the lung by the pulmonary circulation.

This may be caused either by direct shunt through atelectatic alveoli or from inappropriate distribution of ventilation and perfusion in the lungs with large areas of abnormally low \dot{V}_A/\dot{Q} . Arterial hypoxemia is the manifestation of this abnormality. It may be quantitated by the following equation. (1)

$$\dot{Q}_s/\dot{Q}_t \approx \frac{C_c O_2 - C_a O_2}{C_c O_2 - C_v O_2}$$

Pulmonary capillary oxygen content is calculated from a knowledge of the alveolar oxygen tension and high hemoglobin concentration.

$$C_c O_2 = (p_A O_2 \times 0.0031) + (S_a O_2 \times \text{Hgb} \times 1.39)$$

$$C_a O_2 = (p_a O_2 \times 0.0031) + (S_a O_2 \times \text{Hgb} \times 1.39)$$

$$C_v O_2 = (p_v O_2 \times 0.0031) + (S_v O_2 \times \text{Hgb} \times 1.39)$$

If the arterial oxygen tension is above that needed for saturation of hemoglobin, Hgb, the following equation may be used:

$$\dot{Q}_s/\dot{Q}_t \approx \frac{(p_A O_2 - p_a O_2) \times 0.0031}{C_a O_2 - C_v O_2 + [(p_A O_2 - p_a O_2) \times 0.0031]}$$

2. The contribution made to \dot{Q}_s/\dot{Q}_t by direct shunt may be differentiated from that made by \dot{V}_A/\dot{Q} maldistribution by making the measurement in the presence and absence of inert gas. \dot{Q}_s/\dot{Q}_t can therefore be thought of as an index of inefficiency in the lung's ability to deliver oxygen to the circulation.

3. The other major function, the removal of carbon dioxide, can be affected by quite different factors and is commonly measured by solution of the Enghoff modification of the Bohr equation.

$$V_D/V_T = \frac{P_a \text{CO}_2 - P_E \text{CO}_2}{P_a \text{CO}_2}$$

Thus an increase in V_D/V_T represents an increase in ventilatory requirement for a given rate of CO_2 removal.

4. Both \dot{Q}_s/\dot{Q}_t and V_D/V_T can be affected by a change in cardiac output. In addition, alterations in cardiac output can have the most profound effects on systemic metabolism in severely ill patients. This has been one of the most neglected measurements in critical care medicine, primarily because of the difficulty in making rapid and accurate measurements in the clinical setting. The most common methods have been the dye dilution technique and the solution of the Fick equation.

$$\dot{Q}_t = \frac{V_{\text{O}_2}}{C_a \text{O}_2 - C_v \text{O}_2}$$

The latter has been inadequately utilized because of the difficulty in determining oxygen consumption in a patient on positive pressure ventilation. This would be a simple, routine procedure with a flow meter-mass spectrometer package permitting continuous breath by breath analysis.

5. CO_2 production measurement is the analog of the oxygen consumption calculation. This measurement is of use in itself, but also allows computation of the respiratory exchange ratio and the respiratory quotient, RQ. The former is determined by short-term respiratory events and the latter reflects longer-term metabolic changes.

$$R = RQ = \frac{V\text{CO}_2}{V\text{O}_2}$$

RQ allows the physician to follow systemic metabolic activity and is suggestive of alterations in metabolism when it falls outside the range 0.7-0.9.

6. Indirect cardiac output measurement.

It has been a dream among respiratory physiologists for a very long time that it should be possible to estimate mixed venous blood gases, and eventually total cardiac output from measurement of respiratory gases alone, without blood samples or cardiac catheterization.

The old "indirect Fick" was a step in this direction, but for years little progress was made until the work of Dubois, and then Kim, Rahn and Farhi⁽³⁸⁾ demonstrated that in a prolonged expiration, if the instantaneous "R" is plotted against expired pCO_2 , the result is a straight line, which intercepts the true mixed venous pCO_2 at approximately "R" of 0.32, and whose slope is directly related to the arterio-venous difference in oxygen content.⁽³⁹⁾ Bickel then showed that the computation could be programmed into an analog computer so that the plot could be written in real-time, using the sensed signals from a mass-spectrometer. If such a computation were to be combined with the oxygen uptake values already available in real time in our monitoring system, the Fick cardiac output would be available from respiratory measurements alone.

The importance of the development of this technique is obvious; it would give us a valuable clinical tool for evaluation of the patient, as well as a valuable research tool for evaluation of drug or other therapy.

APPENDIX B

Pulmonary Function Testing: Fundamental Equations for Typical Tests

1. Ventilation Study

(a) Dead Space to Tidal Volume Ratio

$$V_D/V_T = (p_a \text{CO}_2 - p_E \text{CO}_2)/p_a \text{CO}_2$$

The measurement is accomplished by respiratory and blood CO_2 tension measurement only, and can be carried out solely by mass spectrometry.

2. Lung Volumes

(a) Functional Residual Capacity by Nitrogen Washout

$$\text{FRC} = \frac{\int_0^t p_E \text{N}_2 \times V dt}{p_A \text{N}_2}$$

A flowmeter and mass spectrometer, in conjunction with an analog or digital computer can accomplish this measurement.

(b) Total Lung Capacity

$$\text{TLC} = \text{FRC} + \text{VC} - \text{ERV}$$

Vital Capacity (VC) is total expelled volume in a forced expiration after maximum inspiration. It can be measured by integration of the flow signal. Expiratory reserve volume (ERV) is the maximum expelled volume from normal end of expiration. It is also measured by integration of a flow signal.

3. Diffusion

- (a) Pulmonary Diffusing Capacity (DC_L) by Single Breath Carbon Monoxide (CO) Uptake.

$$DC_L = (FRC + \int_{\text{inspiration}} V dt) \times \frac{60}{t (p_B - 47)} \times \ln \frac{p_{A\text{CO}} (\text{initial})}{p_{A\text{CO}} (\text{final})}$$

Again, a combination of respiratory CO tension and flow measurements provides the desired result.

APPENDIX C

Mass Spectrometry. State of the Art

A brief discussion is included here of results and problems with respiratory monitoring mass spectrometers.

1. Perkin-Elmer Medical Mass Spectrometer *

This mass spectrometer is a version, for civilian use, of the NASA device discussed in the body of the report. In general, performance over the first four months operation period was satisfactory. Sensitivity for O_2 , CO_2 and N_2 channels has been very stable. A two and one-half percent error in going from room air to 100% oxygen has been observed. Stability is enhanced by a servo mechanism which sums the outputs of the collectors and normalizes species fractions according to the sum. Results for the water channel have been unreliable, perhaps due to condensation in the inlet line. Difficulty has been encountered with the sampling system. Condensation in the inlet line has necessitated experimentation with various plastic cannulae and an inlet heating system. Best results have been obtained with a six foot Teflon cannula with inlet heating. One parts failure was observed; the vacuum pump developed an oil leak. A program is now being written for breath-by-breath computation of oxygen consumption, in conjunction with a Statham ultrasonic flowmeter. Acceptance of the mass spectrometer by nursing personnel is very good.

An ion pump, rather than a diffusion pump used in other mass spectrometers, provides for a slightly faster response. Experimentation with a second mass spectrometer at Pomona revealed a very sensitive, very stable machine with a seventy-five msec ninety percent response to a concentration step function. Sampling was not precise enough to pick up the

* This section is based upon a progress report to Perkin-Elmer from Dr. Reed Gardner (Latter Day Saints Hospital, Salt Lake City) and a visit to Perkin-Elmer-Pomona.

drop in pO_2 associated with dead space equilibration of water vapor. (31)² However, response time is sufficient for accurate calculation of O_2 consumption and CO_2 production by the technique described in Appendix I. Seven channels are available.

2. Beckman Instruments Breath Analysis System^{*}

Beckman has been supported under contract to NASA-Houston to implement a mass spectrometer-computer system for breath-by-breath respiratory measurement and calculation. The system consists of a modified Finnegan quadrupole mass spectrometer and a small dedicated digital computer. A novel feature of the system is the absence of a flow meter, per se. Instantaneous flow is derived from the mass spectrometer analysis of indicator dilutions. Bi-directional injections of Xenon and Krypton provide flow data in phase with the respiratory concentration information. Sampling lag time is therefore eliminated, in theory.

Consideration of airway dynamics suggests that flow error due to inspiratory pressure fluctuations and sampling tube condensation, and non-uniform indicator mixing in the airway may prove to be difficult problems to solve in practice. Also, a less expensive indicator might be preferable for civilian use. Nevertheless, the system has merit, and support from NASA for solution of some of these technological problems is continuing.

3. SRI Medical Mass Spectrometer^{**}

An SRI mass spectrometer has been in continuous use in an intensive care ward at Presbyterian Hospital,

^{*} This section presents a synopsis of conversations with Mr. Radar, Beckman-Fullerton, and Dr. Rummel, NASA-Houston.

^{**} This section reports on a Scientific Research Institute (SRI) spectrometer system at the Institute of Medical Sciences, San Francisco.

San Francisco, in combination with the computer-based monitoring system described in Appendix I. This system has provided stable sensitivities on O_2 , N_2 , and CO_2 channels due to a servo mechanism operating on the summed outputs of the three collector channels. Response time is slower than the Perkin-Elmer device, 700 msec for ninety percent response to a step function, including a third stage to the inlet system. The three stage inlet system, and a five percent duty cycle on each sampling line with dry gas flushing in between distortions due to operation with humidified respiratory gases. The system has an automatic lag measurement and gas calibration system⁽³⁶⁾ which injects gases of known concentration at the airway end of the sampling line. This has proved very reliable and helpful and worth the extra equipment at the bedside. Oxygen consumption calculations have agreed well with determinations based on a reversal of the Fick calculation.

There have been several equipment problems resulting from continuous use. The electron source filament in the ion source has burned out twice; while shorts appear to be involved in these malfunctions, the possibility of decreased lifetime of the Rhenium filaments in an oxygen-rich or contaminated environment cannot be ruled out. Instability in ion current has recently been observed, and the cause is not yet known. Sporadic distortions in the concentration step function response curve have been observed. These are due to instrument, not sampling problems, of unknown etiology. It may be that the spectrometer duty cycle will have to be reduced, under computer control, in order to extend the mean time between failures. Engineering development of this instrument might prove to be more expensive than that for the Perkin-Elmer device.

In general, the impression is that the mass spectrometer is quite adaptable and feasible in the ICU environment. Results are certainly improved over previous methods of O_2 and CO_2 flux measurement.

4. Other Developments*

Since the time of the NASA survey of mass spectrometers (Appendix D), other developments have occurred which date some of the comments which appear there and which bear on the use of such devices in a clinical setting. At New York University Medical Center and at the University of Minnesota, spectrometers have been used to measure blood gases as well as respiratory gases. At Minnesota a quadrupole device is being used. Early problems with stability of the device appear now to have abated somewhat. Further, the University of Maryland is developing a magnetic sector device for use in their trauma unit.

* Since this report was drafted, further information on the University of Minnesota and University of Maryland experiences has been collected. It is reported in Attachment A, and summarized in the covering "Summary Statement on Pulmonary Care Technology Transfer."

APPENDIX D

Summary of Results of NASA-sponsored
Comparative Study of Eight Mass Spectrometers

4.1.4 COMPARISON OF THE SINGLE FOCUSING MAGNETIC AND QUADRUPOLE ANALYZERS

Now that the initial analyses of the magnetic and quadrupole analyzers have been completed, a comparison of their relative merits can be made. The analysis of each of these mass separating techniques was based upon the same sensitivity and resolution and similar ion source requirements. The comparison must be made based upon the support electronics requirements, reliability, environmental, and demand factors.

First consider the weight demand of the two analyzers. Using known weight information for a small quadrupole analyzer with the same r_0 (taking into account the reduction in rod length from 6 inches to 3 inches) and comparing this against the estimated magnetic analyzer weight, it was found that the quadrupole analyzer would weigh approximately 0.25 pounds more than the magnetic analyzer. This difference is due primarily to the quadrupole rods and rod supporting structure. The magnet weight for the magnetic sector analyzer is calculated to be 0.9 pounds (see Section 4.1.6), and this is paired off against the quadrupole power of 1 watt using the 0.5 pound/watt power penalty so that the total effective analyzer weight difference is 0.15 pounds in favor of the quadrupole analyzer.

Next the analyzer electronics must be compared. The magnetic sector requires no electronics for its operation. The mass resolution is obtained solely by the action of the permanent magnet. On the other hand, the quadrupole analyzer requires an rf oscillator and V_{d0} supply. Both the frequency and voltage of the oscillator output must be tightly controlled as shown in Section 4.1.7. This necessitates the use of a feedback control loop and voltage regulator to supply a controlled $B+$ to the oscillator which maintains V_{d0} constant.

Since there are four masses of interest, the frequency of the oscillator must be variable to four values. This is most efficiently done by switching in inductance and capacitance to vary the tank circuit resonating frequency. Each of these tank circuits must be capable of fine tuning. A sequential stepping logic circuit is required to switch the tank circuits. This circuit has the form of a clock pulse and shift register with relay drivers to drive the reed relays. This total system would be very similar to the one used on an existing miniaturized quadrupole mass spectrometer system. It has been weighed at 1 pound 11 1/2 ounces. It is doubtful that this number could be reduced by more than 25% and so a weight value for the quadrupole electronics of 1.3 pounds will be used for comparative purposes. Adding this weight difference to the value for the analyzer gives a total weight difference of 1.15 pounds in favor of the magnetic sector analyzer. The magnetic sector instrument will use four detectors with an additional weight of 0.4 pounds and a minor increase in power. Subtracting this from the previous difference value gives a 0.75 pound advantage to the magnetic sector. From the standpoint of demand factors, the magnetic sector has a clear advantage over the quadrupole analyzer.

Next, the relative reliabilities of the two approaches must be considered. The quadrupole electronics require over 200 electronic components of all types. This would represent a 50% increase in the number of electronic components in the sensor system based upon a magnetic analyzer. On a component count basis alone, a quadrupole sensor system would be considerably less reliable than the magnetic sector instrument. Experience has shown that more problems are encountered with the quadrupole electronics than with the other support electronics areas so that the net result is a much less reliable instrument.

In addition, the single ion current detector used with the quadrupole analyzer must have two sensitivity ranges, necessitating a range switch driven by the logic. This is one further unreliability in series with the output. On the other hand, the multiple detectors employed by the magnetic sector analyzer offer a degree of functional redundancy since the two high level and two low level detectors are interchangeable.

It is also of interest to look at the operational features of the two instruments. The quadrupole analyzer must operate in a serial mode looking at each mass one after the other. On the other hand, the magnetic sector sensor would use a multiple collector system with separate output channels. This gives a time response advantage to the magnetic sector instrument since it will give continuous parallel outputs. Parallel outputs should also make the instrument more compatible with the control system since no serial to parallel switching or signal holding circuitry will be required.

A further possible disadvantage of the quadrupole analyzer lies in the increased difficulty in meeting a tight EMI specification which would probably be imposed on a flight instrument. This difficulty arises not only from the presence of the rf signal but also from wideband noise transients caused by the switching of the tank circuits.

In summary, it must be concluded that the single focusing magnetic sector analyzer has significant advantages over the quadrupole analyzer in terms of power and weight demands, performance, reliability, and interface compatibility. Therefore, the single focusing magnetic sector analyzer was selected as the basis for the sensor system, and all further discussion relates only to this analyzer.

5. REFERENCE TWO GAS ATMOSPHERE SENSOR SYSTEM

The detailed analysis presented in Section 4 has led to the conceptual design of a two gas atmosphere sensor system. This conceptual design is the reference system which is discussed in the Statement of Work. The definition of this system is the principal and product of this study program. In order to insure that it has been adequately defined, the following discussion is given. It includes a summary description; discussions of operational characteristics, power, weight and size requirements, environmental compatibility, reliability, maintainability, and calibration, and the state of development of the proposed instrumentation, its improvement potential, and adaptability.

It is to be emphasized that the system described here represents only a conceptual design. While a great deal of thought has gone into this conceptual phase, it is inevitable that changes will occur during the design phase. It is also likely that refinements of various types may be added at a later date in order to make the sensor compatible with a specific spacecraft environment. Some of these possibilities are discussed later in this section.

5.1 DESCRIPTION

The reference two gas atmosphere sensor system utilizes a small single focusing magnetic sector type mass spectrometer. This analyzer utilizes a non-magnetic, dual electron gun, high differential pumping ion source with a parallel plate ionizing region and a perfect imaging type of ion focusing. This ion source uses two 0.003 inch diameter tungsten-rhenium wire filaments for electron emission. Other filament materials may be selected after an experimental investigation of the properties of several emitters. The ion source is mounted in a thin-walled housing which is an integral part of the analyzer envelope and collector flange assembly. The mass resolution is accomplished by the action of the magnetic field (from an Alnico V permanent magnet) as the ions pass through the envelope section of the analyzers. The four gases of interest will be separated and collected in separate ion collectors which are mounted on the collector flange. These gases are H_2O , N_2 , O_2 , and CO_2 which correspond to ion mass to charge ratios of m/e 18, m/e 28, m/e 32 and m/e 44. The important parameters of the analyzer section are given in Table 4-3.

The cabin atmosphere will be admitted to the ion source through a viscous pressure divider inlet system. This consists of a single two meter capillary line, a pump out line with a platinum aperture molecular leak at their conjunction. This system can sample at various points in the cabin or be attached to a suit loop or calibration source.

The internal vacuum necessary for operation of the analyzer will be maintained by pumping to outer space through a pump out tube.

During preflight and launch periods, the analyzer will be maintained in a sealed off condition by the action of a light-weight bellows valve in the pump out line.

Each of the collected ion currents will be amplified to the required output level by an all solid-state electrometer amplifier. Each amplifier is set for the sensitivity commensurate with the expected sample range of that atmospheric component.

The support electronics consists of only three modules; the filament supply and emission regulator, the ion source electrode bias supplies, and the detector power supply.

The filament supply and emission regulator circuit is a closed loop control system which detects the ionizing electron current collected at the anode and regulates the current supplied to the filament as required to keep the emission current constant. Two alternate circuits will be investigated for this task. The first employs a switching voltage regulator which is driven by a voltage controlled oscillator which is driven by the anode current signal. The second technique utilizes a pulse duration modulator which allows the filament current to be maintained as an ac signal at all points in the circuit. In either of these systems an inverter is required to float the system and the filament is operated in an ac mode.

The electrode bias supplies consist of two stacked high voltage supplies which drive a high impedance voltage divider. Sample voltages from the divider string are fed back to the primary where the regulation is accomplished by use of series regulators on the inverter $B+$ voltages. The voltages required for the ion source electrodes are tapped off the divider string in the potentiometers and transmitted to them through multi-pin headers in the ion source housing. Low temperature coefficient sensor diodes are also used at one point in the divider string to provide additional regulation of a sensitive voltage.

The detector power supply consists of a single dc to dc converter delivering +15 V and -25 V each of which is regulated by series regulators.

The system components described above are mounted in an O-ring sealed case. The case is fabricated of aluminum by the use of a dip brazing process. Two removable panels allow access to the modules.

5.2 CONFIGURATION

The configuration of the reference sensor system is described in three accompanying figures. A conceptual design of the dual filament ion source is shown in Figure 4-8. The important elements of the ion source are called out in the figure. A cross-section view of the conceptual design of the ionizing region is shown in Figure 4-9. The complete analyzer assembly is shown in Figure 4-34. Here the relative location of the ion source, magnetic and ion collectors are indicated as well as the other important features.

The complete sensor system is depicted in Figure 4-55. The salient features of the packaging and the location of the subsystem components are clearly shown, in addition to the expected overall dimensions.

3.3 PERFORMANCE

The expected performance parameters for the reference system are given in Table 3-1.

TABLE 3-1
Expected Performance Parameters

		System Parameters			
Cases to be Monitored	System	H ₂ O	H ₂	O ₂	CO ₂
Resolution (m/m)		1/17.5	better than 1/7.5	better than 1/7.5	better than 1/9.5
Minimum Detectable Pressure Change		0.2 torr	0.4 torr	0.4 torr	0.2 torr
Sample Pressure Level for Maximum Channel Output (5 V)		20 torr	200 torr	200 torr	20 torr
Sensor Linearity within 2% up to a Total Pressure of	400 torr				
Output Voltage Range (Line r)		0 to -5 V	0 to -5 V	0 to -5 V	0 to -5 V
Detector Time Response (One Time Constant)		1 sec	0.2 sec	0.2 sec	1 sec
Capillary Inlet Line Time Delay		10 sec	0.4 sec	0.4 sec	0.4 sec
Maximum Total Pressure 800 torr above which Instability may occur					

3.4 INTERFACE REQUIREMENTS

The following is a list of interface requirements for the reference sensor system.

3.4.1 INPUT POWER

The input power is assumed to be $28 \pm 1/2$ V_{dc} and power ground. A less regulated voltage source will require the use of an input voltage regulator as described in Section 4.6.5. If input isolation is required, an isolating dc to dc converter can be supplied as discussed. It is recognized that power supply voltages generally are not clean but have ac components. When specifications covering this area become available, specific recommendations can be made.

3.4.2 INPUT COMMANDS

The sensor system is turned on and off by a remote command which supplies or cuts off the 20 volt power. In other words, there are no provisions for an on-off command to be received directly by the sensor. A manual toggle switch will be provided to place the instrument in a zero check mode. A toggle switch will also be provided for switching between one filament and another. Both switches will be mounted in the front cover.

3.4.3 SAMPLE INLET

A single flexible two meter capillary line will accept the sample gas. Provisions for heating the line will not be included at this time.

3.4.4 OUTPUTS

There will be four system outputs; one corresponding to each of the sampled gases. All outputs are 0 to -5 V with an output impedance of 500 ohms in the operating frequency range.

3.4.5 ELECTRICAL CONNECTIONS

The input power will be supplied through a connector located at the base of the rear panel. The output signals will be delivered through a standard 'C' series connector which is also mounted at the base of the rear panel. These connectors are different so that a misconnection cannot occur.

3.4.6 VACUUM CONNECTIONS

The analyzer pump out tube shall be approximately one inch in diameter and shall project through the rear of the package. It will connect to the pump out line with flanges and an O-ring seal. (For laboratory test, a vacuum system can be mounted at this point.) A second pump out line of smaller diameter (1/4 inch) will also project through the rear of the package. Connection to this line will be made with a Swagelok type fitting.

3.4.7 ACCESS

Access to the sensor system components will be provided by a dual front cover. The primary cover covers the entire front surface of the package and allows access to all of the modules. A secondary and smaller cover is provided for rapid access to the detector slices for interchanging purposes. Both covers will be hermetically sealed. These gaskets will not be of the RFI shielding

type. Access will also be provided for adjustments which must be made in flight. These parts will be in the front cover and will also be hermetically sealed.

5.4.8 ADJUSTMENTS

External adjustments in the form of potentiometers will be provided for the following purposes:

- a. H_2O detector zero adjust
- b. H_2 detector zero adjust
- c. O_2 detector zero adjust
- d. CO_2 detector zero adjust
- e. Ionizing current

Other adjustments will be required for power supply voltage levels and ion source electrode voltages but these are not considered to be normal in-flight adjustments and therefore will only be accessible by removing the front cover.

5.4.9 MOUNTING

The sensor system package is provided with clearance holes for four screws which will mount the package to a flat horizontal surface. The required surface area will be about 30 square inches.

5.5 DESIGN FACTORS

The power, weight, and size estimates for the reference have been accurately estimated based on available information. The basis for the power estimate is given in Section 4.6. The weight and volume estimate were made with the aid of the analyzer and system package drawings. Volumes of all metal members were computed and multiplied by the density of the material in question.

5.5.1 EXPECTED SYSTEM POWER

The expected system power is 4.66 watts. Of this number 3.47 watts is consumed by the filament and filament supply system. The filament assumed for this estimate was 0.003 inch diameter tungsten-rhenium wire. This is believed to be a fairly conservative choice based upon the results of the emitter study (see Section 4.7). Since we do not have conclusive experimental verification that lower power filaments will have the required life in this application, this emitter has been selected.

5.5.2 EXPECTED SYSTEM WEIGHT

The expected system weight is 6.68 pounds. The weight breakdown is given in Table 3-2. The supporting equipment for the sensor system weighs an additional 2.07 pounds. The maximum expected pump out tube length of 13 inches has been used. If this length were reduced the weight of the line and valve would be reduced correspondingly.

TABLE 3-2

Reference System Weight Distribution

<u>Reference System</u>	<u>Pounds</u>
Analyzer Tube (includes pump out tube to flange)	1.1
Analyzer Magnet	0.9
System Package (includes internal structure)	1.3
Electronics Modules*	2.5
Potting	0.23
Input and Output Connectors	0.5
Capillary Inlet Line (2 meters long)	0.1
Control Switches	0.05
Mating Flanges and Swagelok Fitting for Pump Tubes	0.15
Mounting Hardware	0.18
Total Pounds	6.68
<u>Supporting Equipment</u>	<u>Pounds</u>
1-1/8 inches I.D. x 13 inches long x 0.031 inch wall pump out tube	0.47
1 inch bellows valve for pump out line	0.75
Valve and pump out line for sample system	0.2
Extension shaft (18 inches) and handle for large valve	0.2
Extension shaft (18 inches) and handle for small valve	0.05
Calibration Bottle (Flight Weight)	0.4
Total Pounds	2.07

*See Section 4.6.7 for a weight breakdown

5.5.3 EXPECTED SIZE

The reference sensor system is essentially a rectangular box with the following dimensions: Height - 7-1/2 inches; width - 5 inches; depth - 6 inches. In addition to these basic dimensions, the mounting feet and frontcover flange increase the width to an overall dimension of 6-1/16 inches. There is not complete utilization of the package volume in the present layout. A modified design could reduce the volume.

5.6 RELIABILITY

As discussed in Section 7, the design of a high reliability instrument has to be considered as a primary goal for this task. Several techniques have been applied to insure a design of maximum reliability. First, basic design simplicity has been a primary goal. The choice of the magnetic sector analyzer over the quadrupole analyzer leads to a great reduction in the amount of support electronics which the analyzer required. Second, an effort was made to minimize the number of components in series with the output. This was implemented by going to multiple output channels as opposed to single collector and detector. This reduced the complexity of the electrode bias supply (non-scanning) and eliminated the need for a logic circuit or multiple ranges on the detectors. Third, safety margins were applied throughout the design analysis which allow degradation in performance, without a serious effect upon the essential content of the output information. Fourth, a reliability analysis was carried out on a set of electronics circuits which are similar to the proposed design. This analysis indicated that the reliability of the electronics package would be compatible with mission requirements. The details of this analysis are given in Appendix E. As part of this work, a preferred parts list was generated as a guideline for the future design effort. Fifth, redundancy was applied in two areas where the penalty in terms of added demands was low. These areas were the dual filaments in the ion source and the interchangeability of ion detectors. In the first instance redundancy was employed due to a genuine concern over the ability of the component to meet the mission life time requirements.

In the second case, it was applied primarily because of the opportunity to make maximum use of available modules.

In addition to applying the above-mentioned considerations during the conceptual design phase, other similar methods would be applied in the design and fabrication phases. These would include worst case electronics design; careful design of the analyzer and overall package with design reviews to insure that all factors have been adequately investigated, and selection of qualified components in conjunction with component derating.

These combined factors placed in an integrated program from conceptual design through manufacture will lead to a highly reliable instrument.

5.7 ENVIRONMENTAL COMPATIBILITY

The proposed reference system is designed to meet the performance parameters given in Section 5.3 under the following environmental conditions.

5.7.1 OPERATING TEMPERATURE RANGE

40°F to 90°F

5.7.2 VIBRATION

The sensor system will function normally after passing through an Apollo launch vibration profile. Operation is not intended during launch or re-entry of the spacecraft.

5.7.3 EXTERNAL PRESSURE

The instrument can only be operated at altitudes where the ambient pressure is less than 1×10^{-6} torr. Above this pressure stability may not be maintained.

5.7.4 LEAKAGE RATE

The rate of gas loss due to the sample inlet system is less than 0.001 pounds/hour or 1/30 of the total cabin leakage rate.

5.7.5 ZERO GRAVITY OPERATION

There is no problem in operating the sensor system in a zero environment, since its operation is in no way affected by gravitational fields.

5.7.6 EXPOSURE TO HARD VACUUM

Exposure to hard vacuum will not affect any of the sensor system components. It is a potential problem only due to the possibility of a pressure differential across the O-ring sealed case. If this is shown to be a problem, a two-way pressure relief valve can be incorporated.

5.7.7 BURNUP LIFE

The shelf life of the sensor system is limited only by degradation of electronic components. The analyzer tube should preferably be pumped in order to keep it clean, but it can be kept in a "pinched off" condition for long periods of time with no harmful effects.

5.8 ACCURACY

The accuracy of the two gas atmosphere sensor system is controlled by several factors. A brief summary of sources of errors is given below:

- Inlet line memory effects (small except in the case of water).
- Ion source temperature dependences (ionization sensitivity and ion focusing).

- d. Feedback resistor temperature coefficient (compensatable).
- e. Changes in the sample distortion due to filament interaction. (Relatively long term and therefore minimized by calibration; also reduced by differential pumping and the constant nature of the sample.)
- f. Detector zero drift (very small and capable of adjustment).
- g. Variations ionizing current (controlled by the emission regulator).
- h. Variations in the ion source sensitivity due to voltage variations (controlled by power supply voltage regulation).

Examining these sources of error leads to the following conclusions:

- a. Variations due to ambient temperature changes will not be of major significance, due to the relatively small temperature range and partial compensation of different effects.
- b. Variations due to voltage instability can be minimized to the necessary levels by power supply design.
- c. The error due to emission level variation is probably the most significant contributor with a value of about 10.5%.
- d. The overall accuracy should be close to 1% in the normal cabin temperature range ($70^{\circ} \pm 5^{\circ}\text{F}$).

3.9 MAINTAINABILITY AND CALIBRATION

The reference sensor system is designed such that only the following minimal maintenance functions will be necessary in flight:

- a. Checking the zero by throwing the zero check switch and resetting the detector zero levels with a screwdriver potentiometer adjustment. This should be necessary once every few days.
- b. Calibration of the instrument by attachment of the calibration sample source to the capillary input and adjusting the emission current set. This should be required once every one or two days and will take approximately one minute.
- c. Switching the filament if one of them burns out. This is accomplished by rocker switch mounted on the front cover.
- d. Switching the detectors if one becomes inoperative. The O_2 and CO_2 channels are assumed to be of greater importance than the N_2 and H_2O channels. Therefore, if the detector in one of the former channels should fail the latter detector of corresponding sensitivity could replace it. This is done by removing the small front cover and switching two of the slide-in modules.

- e. When the sensor system is first required to operate, the valves sealing the main and sample pumpout lines must be opened. This is done by turning the extension handles which protrude through the bulkhead.

Several calibration sources were considered. It was decided that the most practical one would be a thin-walled high-pressure gas bottle with a pressure regulator which would deliver a known sample pressure when attached to the capillary line. The proposed sample is an oxygen, nitrogen, carbon dioxide mixture.

3.10 STATE OF DEVELOPMENT

The analyses carried out in Section 4 have shown that the design of a mass spectrometer sensor system is an involved process requiring the combination of disciplines from many areas. Experience has shown that a thorough analysis of the instrument during the design phase reduces the problems encountered in the experimental work.

In addition to a firm theoretical understanding, a successful instrument should employ design concepts which have been experimentally proven. This procedure has been followed during this conceptual design. The following is a recap of the important areas in which existing technology is being applied.

- a. Ion Source - Most of the features of the proposed ion source have been experimentally proven in other SDS Data Systems designs. These include the non-magnetic ion source concept, the low ion source conductance, the electron gun design, ion focusing methods, expected sensitivity and emission levels, filament configuration and mounting, and fabrication techniques. The only untested feature of the ion source is the orthogonal electron guns and it is unlikely that any difficult problems will be encountered in this area. Details of the ion and electron focusing must be worked out but the techniques are well understood.
- b. Analyzer - The 90° sector single focusing magnetic analyzer has a long history of proven performance. SDS Data Systems has built double focusing mass spectrometers (90° magnetic sector) which have been flown on Explorer 17 and Cooprobe. These instruments were somewhat more complex than the proposed design due to the addition of an electric sector for energy focusing. The development of this and other instruments has given SDS Data Systems the necessary experience in general fabrication techniques, collector back mounting, characteristics of permanent magnets, analyzer testing, materials selection, vacuum welding, and other facets of analyzer design, fabrication, and testing. The analyzer design concept does not deviate from proven practices in these areas.
- c. Sample Inlet - The capillary inlet line and the ball leak to be used as the molecular flow orifice have both been fabricated and tested on previous NASA contracts. The only deviation is that the diameter profile of the capillary line and the pump out line will have to be modified.

- d. Detector System - The solid-state electronics to be employed as the ion concept detectors are similar in design to existing circuits. The most critical area in the detector design is at the input where high impedance and low noise limitations must be met. The input device to be employed has been shown to meet these requirements through extensive testing.
- e. Support Electronics - The types of power supplies which are required in the support electronics represent state-of-the-art designs. The biggest innovation in their development is the application of worst case design to insure that the circuits will operate reliably under the expected environmental conditions and component degradation. The optimization of circuit efficiency also requires some effort, but similar requirements have been found in the past. A new type of emission regulator will be investigated, however, this is backed up by a slightly modified version of a proven design.

The other aspects of the instrument design are also considered to be within the state-of-the-art. The principal effort required is in the area of design optimization which is concerned for the most part with the diligent application of existing technology.

As has been shown in the preceding discussion, in most instances, the proposed instrumentation is based upon modifications of existing designs. These modifications do, however, imply changes in performance of the various subsystems. Therefore, experimental data for them does not exist, and consequently cannot be presented here. Data from existing mass spectrometer systems could have been given, however, in most cases it would not have any great significance relative to the proposed design.

5.11 IMPROVEMENT POTENTIAL

The reference system represents a realistic approach to the solution of the two gas sensor system. As discussed in the preceding section, it is largely based upon accepted state-of-the-art components. As a consequence, the design is a fairly conservative one, which is in agreement with the philosophy presented in Section 2. There are several areas where additional study and application of more advanced techniques would lead to improvements in the instrumentation. At the same time, changes in the performance or environmental constraints could be reflected in reduced system demands. These possibilities are briefly considered below.

The analyzer optimization which was carried out in Section 4.1.2 was based on an assumption of constant resolution which lead to resolution margins on the m/e 28, m/e 32, and m/e 44 mass peaks. If these margins are reduced, certain parameter changes are implied in the analyzer design which could lead to a weight reduction in the magnet.

The discussions in Sections 3.2 and 6 indicated that the detectable limit requirement which has been imposed is possibly more stringent than is actually necessary to perform the controlling function. An increase in the detectable limit would lead to less restrictions upon the analyzer and consequently improvements could be effected in several areas such as analyzer weight or pumping requirements.

The preliminary emitter study given in Section 4.7 revealed that several possibilities exist for the application of improved filament materials. This could lead to lower filament power and reduced pumping requirements. Since the filament power accounts for a major portion of the total system power, the improvement potential is obvious. It is estimated, for instance, that if a 0.003 inch diameter thorium alloy filament could be employed that the filament power could be reduced to about 0.5 watts. When multiplied by the efficiency factors of the filament supply, and emission regulator the total power saving is over two watts. This would reduce the total system power to less than three watts. An experimental program as outlined in Section 4.7 is strongly recommended to explore this avenue for improvements.

The sample inlet system recommended is based upon the assumption that monitoring the exit loop is a desirable feature of this instrument. Should this prove to be of little necessity, it might then be possible to go to a direct molecular inlet leak which would eliminate the capillary line, and associated pump out line and valve.

There is also potential for improvement in the pumping system. The dimensions and weights given for the pump out line and valve assumed an 18-inch line to be required. More specific information regarding instrument location might indicate that a reduced line length could be allowed. This would allow a reduction in the tube diameter and valve orifice with a corresponding saving in weight.

The possibility of going to an ion pump in place of the pump out tube was described in Section 4.4. This was predicated on a reduction in the pumping speed requirements by allowing a decreased value of differential pumping.

This depends, in turn, upon other factors as pointed out in Section 4.4. This alternative may be made more attractive by improving the ion pump magnet design. The weights given were for standard magnets which do not employ high energy product material.

The area of packaging offers several possibilities for weight reduction. The electronics packaging was assumed to be based upon standard printed circuit board construction. Generally, this type of construction does not allow a very high component packing density. By going to other packaging methods, size and weight reductions can be realized. Several stages of compression could be considered. These range from reduced component spacing and bend radii on component leads (thus deviating from NASA H/C 200-4), Japanese cord wood, and welded wire module, to the use of hybrid integrated circuits. These last two techniques should not be attempted until after the design and performance of the entire instrument is well proven.

Insofar as the overall package is concerned, weight and size reductions can be effected by more efficient space utilization to obtain a more compact package and use of more exotic materials in the case and structural supports.

In conclusion, it can be stated that many areas for improvement in this instrument exist which could substantially reduce its power, weight, and size demands while maintaining the required performance.

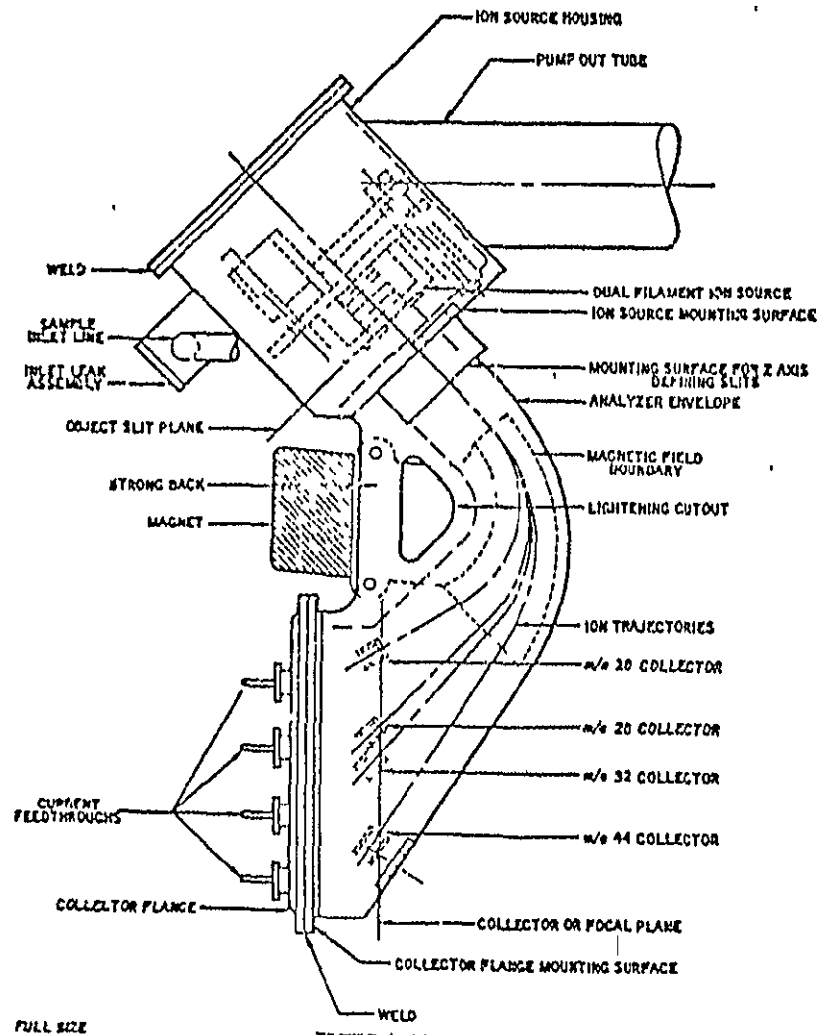


FIGURE 4-55
Analyser Envelope

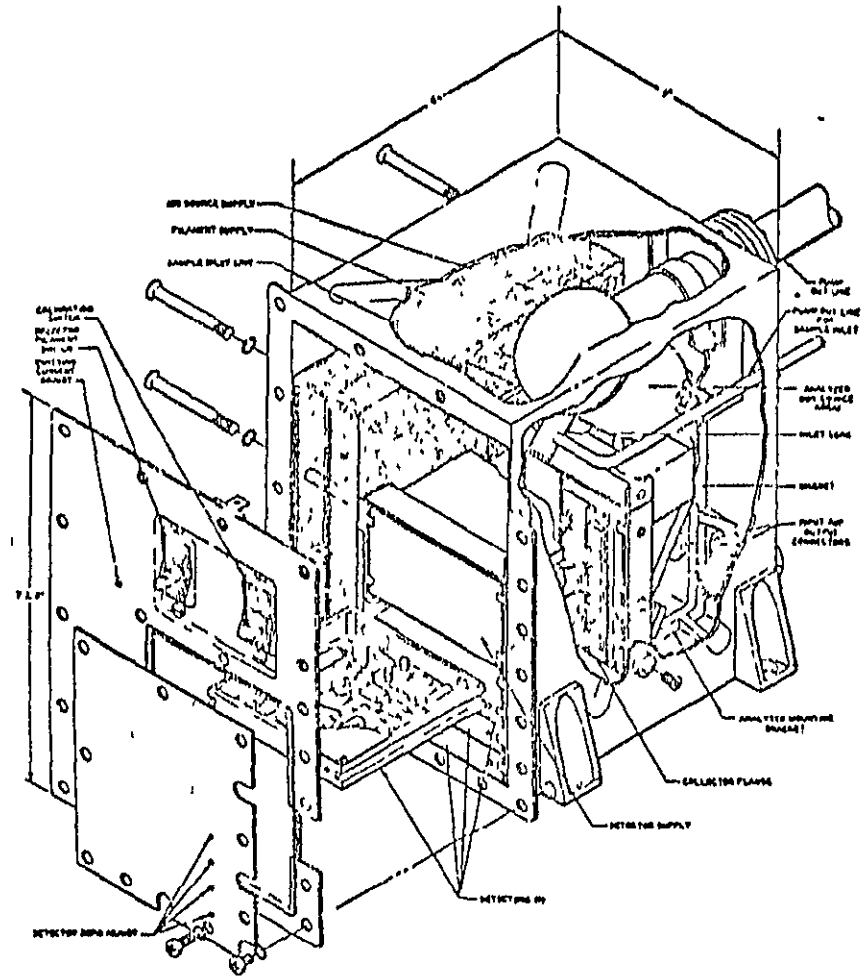


FIGURE 4-56
Conceptual Sensor System Configuration

APPENDIX E

NASA: Mass Spectrometer Specifications

The following measurements in the respiratory area can be provided by gas analysis using a mass spectrometer:

1. Respiratory Dead Space

The subject breathes pure oxygen and the inspired and expired air volumes are measured along with the expired nitrogen concentration. (To accomplish this measurement the mass spectrometer must measure nitrogen mass unit 28).

2. Oxygen Consumption and Carbon Dioxide Production

Respiratory flows, alveolar oxygen, and carbon dioxide partial pressures. To accomplish this measurement the mass spectrometer must measure oxygen and carbon dioxide, mass units 32 and 44. It would be very useful to apply these techniques to patients during surgery and in the early post-operative period. However, they may not easily be employed when using N_2 anesthesia, which has the same molecular weight as CO_2 .

3. Minute Alveolar Ventilation

Calculated from the subject's total expired volume and the fractional concentration of carbon dioxide in the expired breath. (To accomplish this measurement the mass spectrometer must measure carbon dioxide mass unit 44).

4. Cardiac Output

CO_2 rebreathing technique. (To accomplish this measurement the mass spectrometer must measure carbon dioxide mass unit 44).

5. Lung Diffusing Capacity

Single breath technique in which the subject breathes a mixture of helium and carbon monoxide. This test requires a low concentration of carbon monoxide, approximately 0.3 percent. Technical problem: Carbon monoxide ion mass is twenty-eight, the same as nitrogen. The oxygen in the carbon monoxide shall be O^{18} , which results in a mass unit of thirty for the carbon monoxide used in the test. (To accomplish this measurement the mass spectrometer must measure nitrogen mass unit 28 and carbon monoxide mass unit thirty.)

6. Blood Carbon Dioxide and Oxygen

(To accomplish this measurement, Perkin-Elmer is not required to develop a probe, etc. -- only provide a mass spectrometer for detection of oxygen and carbon dioxide mass units 32 and 44.)

The mass spectrometer shall measure mass units as follows:

a. Oxygen (O_2)	32
b. Carbon dioxide (CO_2)	44
c. Nitrogen (N_2)	28
d. Carbon Monoxide (CO)	30 (Using O^{18})
e. Helium (He)	4
f. Water (H_2O)	18

Measurement accuracy and performance specifications required of the mass spectrometer are as listed below. (Use calibration gases to establish during test program.)

<u>constituent</u>	<u>accuracy</u>	<u>Over Mixed Gas Range of</u>
O ₂	$\pm 2\%$	0 to 700 mm Hg
CO ₂	$\pm 2\%$	0 to 140 mm Hg
N ₂	$\pm 2\%$	0 to 670 mm Hg
CO	$\pm 2\%$	0.1 to 2.5 mm Hg
He	$\pm 2\%$	60 to 90 mm Hg
H ₂ O	$\pm 2\%$	40 to 60 mm Hg

Although not all parts of each range may be necessary for routine care, they will be required for accurate physiologic definition of derangement and for investigative flexibility.

APPENDIX F

The Quadrupole Mass Spectrometer

The quadrupole method of mass analysis was less favorable for space flight ratings, but was a close second to the magnetic analyzer. A commercial analyzer of the quadrupole type has been developed in Germany, and results with this device follow: One unique feature of interest in the present context is a three-stage inlet system.

NASA has also experimented with the quadrupole device, in the form of a very small lightweight flow section, which could be mounted on an astronaut's helmet. All supporting electronics and the vacuum system are located at a distance from the astronaut. The system scans four sequential mass peaks at the rate of one peak/msec. Disadvantages of the system are the need for a long flexible vacuum line, and the likelihood of contamination of the molecular inlet leak, due to its proximity to the subject. The concept is attractive and is worthy of long-term support.

The following reports summarize two quadrupole projects under current investigation.

PRECEDING PAGE BLANK NOT FILLED

Patient Monitoring
P.M., Tuesday
17 November

WILSON M. BRUBAKER
Earth Sciences
A Teledyne Company
Pasadena, California



Fig. 1 Mass spectrometer breath analyzer unit worn under astronaut's chin.

A miniature mass-spectrometer system has been developed for use by an astronaut. It fits inside the helmet, under his chin. Most of the electronic components are carried as a back-pack. Breath gas is transmitted through a small tube from the vicinity of the nose to the vacuum chamber, under the chin, as shown in Fig. 1. No electronic portions are included in the display.

Mass analyses are made by a miniature quadrupole mass spectrometer, which makes excellent separations of the mass peaks of breath gas. The instrument makes repetitive scans of the major peaks associated with water vapor, nitrogen, oxygen and carbon dioxide. Thus, an essentially continuous reading is provided for the concentrations of each of these components of breath gas.

An example of the response of the instrument is shown in Fig. 2. In this instance, the instrument was set to respond to carbon dioxide continuously while the subject breathed through a large tube placed in his mouth. Note the fast response of the instrument to the abrupt change in the composition of the breath gas when the direction of breathing is reversed. The change from exhale to inhale was made very abruptly

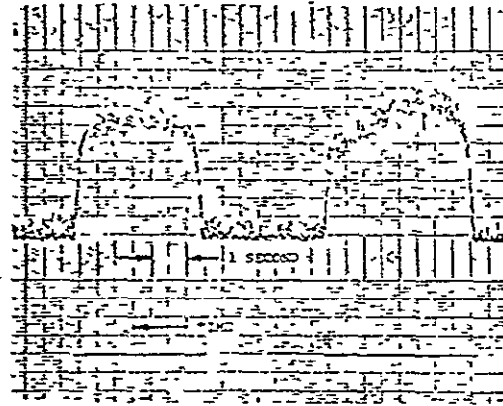


Fig. 2 Sample trace showing system response to CO_2 during inhale/exhale cycling.

by the subject. The time constant of the device's response to a step change in the composition of the breath gas is about 50 milliseconds. This fast response permits the composition to be monitored on a breath-to-breath time scale.

Based on the progress made on the development of a flight-type instrument, specialized laboratory equipment can be designed for use in the operating room or in intensive care units.

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Water Vapour Independent Inlet System For Respiratory Air Mass Spectrometers*)

K. Muysers, L. Delgmann and U. Smidt
Institute of Physiology, University of Bonn (Germany)

Received**) Dec. 18, 1967

Summary. The influence of varying water vapour partial pressure in mass spectrometric analyses of inspired and expired air may cause errors if the conductivity of the inlet system is different for water vapour and for permanent gases. The paper describes a 2-stage and a 3 stage inlet system for the quantitative analysis of expired gases in case of quickly changing water vapour pressure.

Key-Words: Mass Spectrometry — Inlet System — Water Vapour.

Zusammenfassung. Bei massenspektrometrischen Atemgasuntersuchungen wirken sich Änderungen des Wasserdampfpartialdruckes während der In- und Expirationsphase sehr störend aus, wenn die Einlaßsysteme eine unterschiedliche Leitfähigkeit für Wasserdampf und Permanentgase aufweisen. Es werden ein 2- und ein 3-stufiges Einlaßsystem beschrieben, mit denen eine quantitative Analyse auch bei schnell wechselnden Wasserdampfspannungen möglich ist.

Schlüsselwörter. Massenspektrometrie — Einlaßsystem — Wasserdampf

When mass spectrometers are employed in respiratory and metabolic physiology, one of the major difficulties lies in the design of a suitable sample inlet system which is independent of large and abrupt changes of water vapour partial pressure.

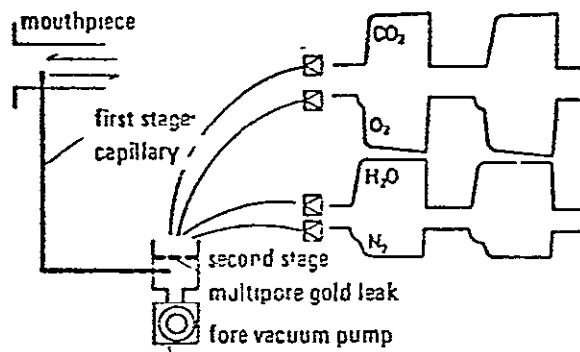
It is the purpose of every mass spectrometer inlet system to reduce the pressure of respiratory gases, from atmospheric to a value permissible by the mass spectrometer, of approximately 10^{-6} torr. The required pressure reduction of almost $1:10^9$ imposes rather stringent conditions on the gas inlet system because the composition of a gas mixture during gas inlet must not be altered by the inlet system.

1) In conventional inlet systems used in mass spectrometric respiratory air analyses in the past, pressure reduction was performed in two stages. As shown in fig. 1 (upper portion), the respiratory air was sampled from the mouthpiece of the patient using a steel capillary 0.5–2.0 m long, with an inner diameter of 0.1 to 0.2 mm. The gas flows through the capillary, passes a multipore gold leak, and is then vented by a fore vacuum pump. Owing to the conductance of the capillary, the pressure is reduced from approximately 760 torr in the mouthpiece to about 1 torr in front of the multipore gold leak (first stage of pressure reduction).

*) This research was supported by financial grants from the Montan-Union — Europäische Gemeinschaft für Kohle und Stahl.

**) The original paper was written in German and published in "Pflügers Archiv", 299, 185–190 (1968).

Two-Stage Inlet System



Three-Stage Inlet System

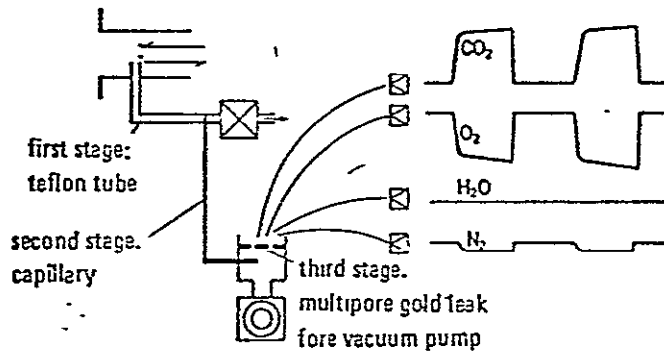


Fig. 1: Comparison (schematically) of the two-stage inlet system (upper portion) and the three-stage inlet system (lower portion) of a mass spectrometer, and of the corresponding expiratory partial pressure curves.

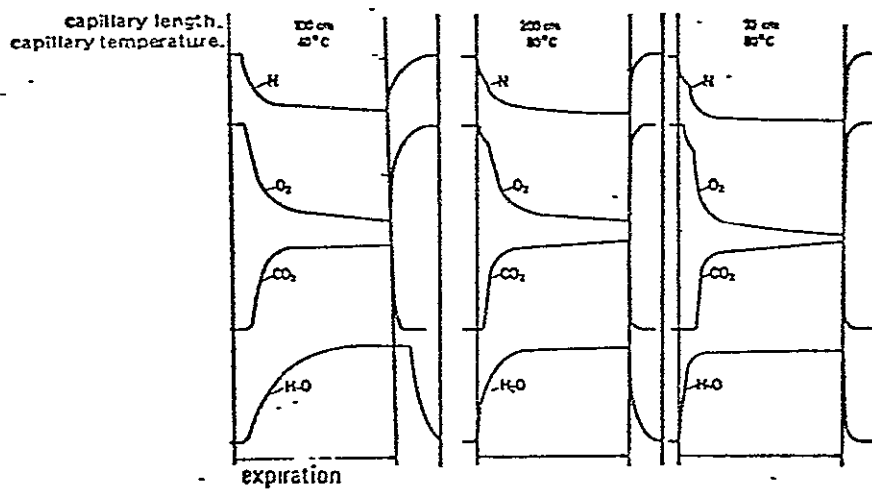


Fig. 2: Simultaneously recorded expiratory partial pressure curves of oxygen, nitrogen, carbon dioxide and water vapour, for different lengths and temperatures of the capillary of a two stage inlet system.

The length and the diameter of the capillary as well as of the gas feed line to the fore vacuum pump are matched such that the gas flow from the mouth piece to the fore vacuum pump is viscous and laminar. This type of gas flow avoids any changes of gas concentration in the first stage of pressure reduction.

The total amount of gas taken from the patient during one respiratory cycle amounts to 5 to 20 ml/min, depending on the length and the temperature of the capillary. Only a very small fraction of this gas enters the mass spectrometer analyzer via the multipore gold leak. The gold leak represents the second stage of pressure reduction. By means of a diffusion pump the pressure is reduced from 1 torr in front of the gold leak to 10^{-6} torr in the mass spectrometer analyzer region.

The gas penetrates the multipore gold leak in molecular flow because, at a pressure of 1 torr, the pore diameters of the gold leak are small in comparison with the mean free path of the gas molecules. Since in the mass spectrometer we have molecular gas flow owing to the low pressure in the analyzer region, likewise no change of the gas concentration occurs in this second pressure reduction stage. Therefore, gas mixtures arrive at the analyzer in their original composition.

These assumptions, however, are valid only for mixtures of permanent gases. Owing to the fact that water vapour pressure varies strongly in inspiratory and expiratory air, a rather disturbing effect may occur in continuous analyses during respiratory air investigations if the conductance of the inlet capillary differs for water vapour and for permanent gases (DELGEMANN, 1966). Fig. 2 shows the simultaneous recording of partial pressure curves, during the expiration phase, of nitrogen, oxygen, carbon dioxide and water vapour when using capillaries of different lengths (70, 100 and 200 cm) and at different temperatures (40 °C and 80 °C). It is clearly evident that the expiratory increase of water vapour partial pressure, when using a capillary of 100 cm length and 40 °C, is delayed considerably relative to the other gas components of the mixture. This difference is even more pronounced when the inspiratory partial pressure decreases. Although inspiratory air flows into the sample inlet system with a considerably lower water vapour partial pressure, a water vapour partial pressure of 47 torr is recorded for another 300 ms. It follows that water vapour requires more time to travel through a cold capillary than permanent gases.

This phenomenon impedes the simultaneous recording of changes in partial pressure of permanent gases and water vapour. In addition, the conductivity of the capillary for permanent gases is affected by the changing pressure of water vapour which in turn results in a change of recording sensitivity. The effect of gas fractionation is strongly reduced if the capillary is heated to a temperature of 80 °C over its total length. Only if the length of the capillary is reduced to 70 cm, differences in conductivity for water vapour and permanent gases are no longer observed. Short capillaries will, however, inconvenience the patient if investigations are performed during certain stress conditions, and they may cause problems in the positioning of other instruments required for the investigation in the laboratory.

A closer look at the expiratory nitrogen and oxygen curves indicates another effect due to the change of pressure of water vapour which must be considered for calibration. Immediately after the start of the expiration phase, the pressure of water vapour increases quickly to a value of 47 torr while the pressure increase of carbon dioxide and the pressure decrease of oxygen and nitrogen only starts after the absolute dead space volume has been expired. If during expiration of the absolute dead space volume (which can be recognized by the fact that no carbon dioxide is yet expired) the concentration of oxygen and nitrogen decreases, then this effect cannot be attributed to reduced conductivity of the capillary but is caused by an apparent change of the total pressure of all permanent gases. The reason for this effect is that the pressure of water vapour increases while the total pressure remains constant.

For a number of physiological problems in which the response with time of water vapour pressure during expiration is of interest, the gas sample is usually taken from the patient using a short capillary, heated to 80 °C, and sampled by the two-stage inlet system. For pulmonary function studies in which only the partial pressures of permanent gases are measured, the change of water vapour pressure from inspiration to expiration must be considered when using the two-stage inlet system. A calibration method and an apparatus for this purpose have been described by HERTLE (1966).

2) In order to simplify calibration, and to improve the conditions for the analysis of expiratory partial pressures of permanent gases, a three stage inlet system was developed which guarantees constant water vapour pressure within the second and third stage (MUYSEERS et al., 1967). The first stage consists of a teflon tube (inner diameter 1 mm) by means of which the gas sample is continuously sucked off from the mouthpiece of the patient by a small membrane pump. The length of the teflon tube may vary between 0.5 and 3.0 m, and is noncritical as far as the response time of the instrument is concerned. The second stage consists of a short (40–70 cm) capillary which may or may not be heated, the third stage of the inlet system consists of the multipore gold leak (fig. 1, lower portion).

After only a few breathing cycles, water vapour condenses on the inside wall of the teflon tube because the expiratory air cools off from 37 °C to room temperature. The water deposits as a thin film and causes, during the inspiration phase, saturation of the drier inspiratory air such that in the second and third stage of the inlet system the water vapour pressure remains constant. Therefore, changes of water vapour partial pressure between inspiratory and expiratory air are no longer observed.

Fig. 3 shows an experimental curve of water vapour pressure in the second stage of the three-stage inlet system as a function of the temperature of the gas samples which were saturated with water vapour and brought to the required temperature in a thermostatically controlled frit bottle. It is clearly evident that, at temperatures below room temperature, the measured water

vapour pressures correspond to the values of maximum saturation. The water vapour pressure, however, never exceeds the saturation value at room temperature if the gas sample is raised to higher temperatures. It follows that the gas assumes room temperature in the teflon tube. Therefore, its water vapour pressure at this temperature can only increase to the saturation value. The three-stage inlet system just described yields, therefore, constant water vapour partial pressure during inspiration and expiration. As a consequence, the partial pressures of permanent gases are exactly defined during each phase of breathing. The calibration procedure, using dry calibration gas, imposes no difficulties because the water film in the teflon tube ensures, for a period of approximately 2 minutes, saturation of the calibration gas with water vapour. Compared to a flow of 0.01 to 0.1 ml/s of gas for the two-stage inlet system, the gas flow required in the first stage of the three-stage inlet system amounts to 1 ml/s. While gas flows of this magnitude are noncritical even in case of human subjects with very small endexpiratory air flow, the application of the three stage inlet system may no longer be possible when investigating small animals.

Fig. 1 schematically shows the two-stage inlet system (upper part of the figure) and the three-stage inlet system (lower part of the figure), together with the corresponding expiratory partial pressure curves of water vapour, oxygen, carbon dioxide and nitrogen. In particular during the starting phase of the expiratory oxygen and nitrogen curves, the influence of water vapour pressure variations from partial to complete saturation is quite noticeable for the two-stage inlet system. This effect is entirely missing in case of the three-stage inlet system in which the water vapour pressure, as clearly evidenced in the figure, remains constant during inspiration and expiration.

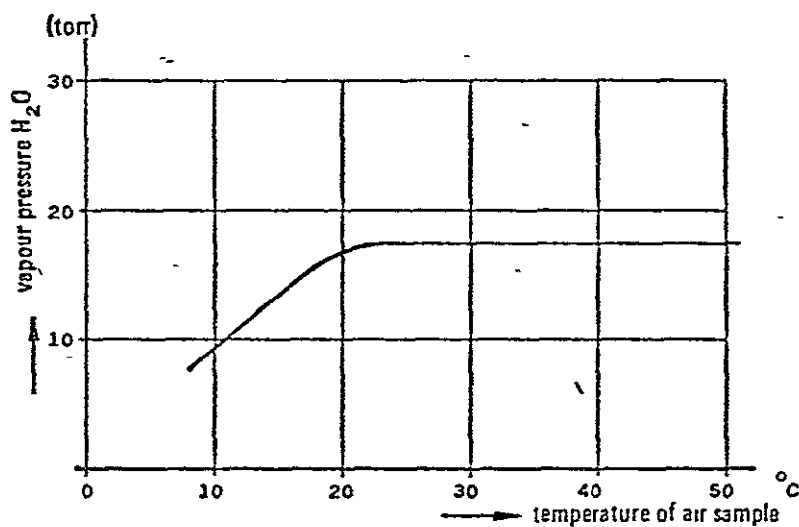


Fig. 3: Water vapour partial pressure, determined mass spectrometrically, of fully saturated air samples at different temperatures, for the three-stage inlet system. Room temperature 20 °C.

A considerable advantage of the three stage inlet system is given by the fact that in case of shape analyses of expiratory partial pressure curves no distortion arises due to variations in water vapour pressure.

A further advantage of the three-stage inlet system consists in its insensitivity towards contamination by saliva and dust. The teflon tube (first stage) may be changed within seconds if accidentally saliva has been sucked together with the respiratory air. Dust particles suspended in the surrounding air are to a large extent sedimented on the wet walls of the teflon tube, thus they cannot impede the conductivity of the capillary by partial obstruction.

The first stage of the three-stage inlet system may in an analogous manner be used in all gas analyzers which exhibit a cross sensitivity with respect to water vapour pressure. This is, for example, evidenced in the analysis of oxygen partial pressure in the ultra-violet spectrum, or when using thermal conductivity cells.

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APPENDIX G

Specifications for Advanced Development of the NASA Mass Spectrometer

Blood gas tensions place the most stringent requirements on precision.

The Hgb-O₂ dissociation curve indicated that, for venous blood, a pO₂ error of one mm Hg leads to as much as a two percent absolute error in oxygen saturation, or a 0.3 vol % absolute error in oxygen content. One mm Hg is the standard error of the best clinical model polarographic oxygen analyzer. It should also be the minimum specification for the mass spectrometer.

The calculation of CO₂ content from pCO₂ and pH via the Singer-Hastings nomogram shows that a pCO₂ error of one mm Hg can cause as much as a 0.6 vol % error in CO₂ content. Calculation of CO₂ content from pCO₂ and pH neglect the CO₂ transported in the carb-amino form by hemoglobin. While this accounts for only about two percent of the total CO₂, it accounts for thirty to fifty percent of the CO₂ exchange. Therefore, these calculations provide grossly misleading estimates for CO₂ production. (40)

Respiratory gas calculations require frequency response. Computer-based breath-by-breath O₂ flux computations are obtained at the Pacific Medical Center, San Francisco, (Dr. John Osborn), by the following technique, and are instructive for the pulmonary monitoring problem. Instantaneous flow, V(t), is obtained by direct airway measurement, with a lag essentially zero. Instantaneous oxygen tension pO₂ (t) is obtained by sampling at one L/min down a twelve foot tube from the airway, (a three stage inlet system is employed). A typical tracing is shown in Figure A-1. Note that the flow and O₂ fraction signals are out of phase. There additionally may be distortion of the oxygen signal due to axial mixing, wall condensation and diffusion, mixing effects at elbows, orifices, etc. and response time of the mass spectrometer itself. Oxygen flux is the product

$$K \cdot \dot{V}(t + \tau) \cdot pO_2(t)$$

and oxygen volume per half breath follows by integration. Note that inspired and expired volumes are very large, and oxygen consumption per breath is typically only three percent of tidal volume. This subjects the calculation to serious errors from small discrepancies in flow or oxygen fraction.

It is very important that the lag time, τ , be accurately known. Table A-1 lists oxygen consumption calculations for various assumed lag times. An error of 128 milliseconds in τ produces a nine percent change in computed oxygen consumption. The primary cause of the error is the weight of high oxygen fraction and high instantaneous flow at the beginning of expiration. Since we may expect rather long sampling lines in pulmonary monitoring, it becomes important to accurately determine the lag.

Distortion is present in this signal, as can be noted with reference to the oxygen curve of Figure A-1 at beginning of inspiration. It takes approximately 160 msec to achieve ninety percent of the response to a step function change in PO_2 . In addition, the water vapor compensation step to the PO_2 curve at beginning of expiration is not observed⁽³¹⁾ with a faster response instrument. A rigorous quantitative estimation of the effect of distortion error on computed oxygen uptake is not available as can be seen with a faster response instrument. A rigorous quantitative estimation of the effect of distortion error on computed oxygen uptake is not available as of this writing. However, semi-quantitative evidence indicates that a response curve similar to that given in Figure A-1 can provide sufficient accuracy for clinical purposes. (This statement is based on comparison of on-line computed oxygen uptakes, including distortion, with simultaneous reverse Fick determinations of O_2 uptake, for actual patients.)

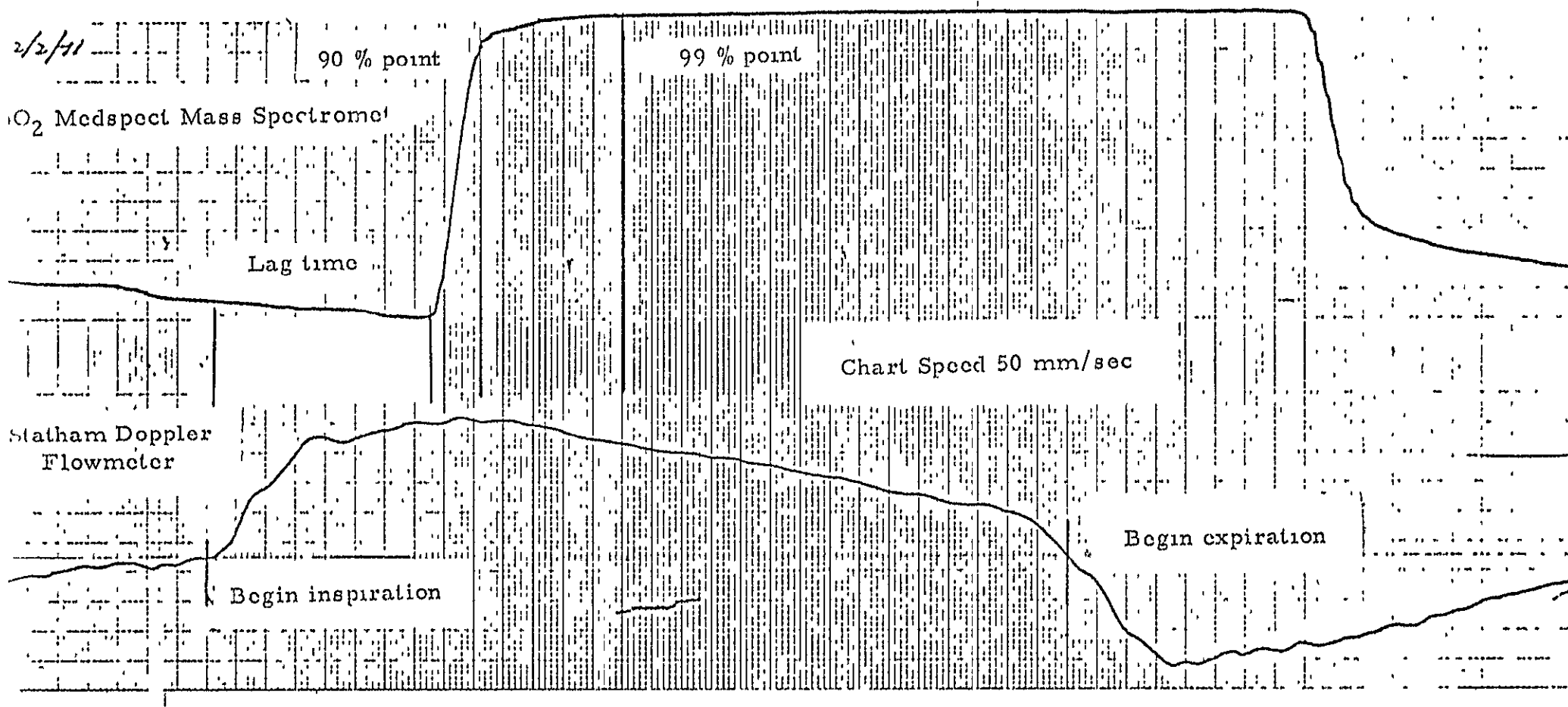
A separate catheter for respiratory gases should be included in the ventilatory circuit. Suitable phasing and distortion adjustments, required by the long sampling lines, will be made. Computations are most effectively carried out in real time by analog or digital computer. In the event of substantial sample distortion, digital filtering is the method of choice for reconstruction of the sample pulse. For gas flux calculations, an in-line flow meter must be provided. An in-line pneumotachograph has been used

TABLE A-1

Effect of Lag Between Flow and Concentration Signals on the Breath-by-breath Calculation of O_2 Consumption and CO_2 Production

<u>LAG, msec</u>	<u>GAS FLUXES, ml/min</u>		<u>% ERROR</u>	
	<u>O_2</u>	<u>CO_2</u>	<u>O_2</u>	<u>CO_2</u>
-128	407	371	- 10%	- 9%
- 64	432	391	- 5%	- 4%
0	453	408	0	0
+ 64	469	423	+ 3.5%	+ 4%
+128	483	433	+ 6.5%	+ 6%

Figure A-1



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for flow measurements, but provides many problems in chronic use. The numerous pitfalls of the method are described by Osborn et al ⁽⁴¹⁾ and summarized in Appendix I. The corrections summarized therein must be included in any system involving semi-continuous sampling and gas analysis at a distance from the patient.

Long-term signal drift, due to ion source filament changes, ion current variations, ion output energy shifts, trajectory instability and collector electronics drift, should be such that the blood gas precision specification can be maintained with only one recalibration per day. Stability is also affected by intrabreath pressure fluctuations. For respiratory calculations, the deflections in response should be less than 5 mm Hg for a 60 cm H₂O change in airway pressure.

APPENDIX H

Catheter Tip Specifications

The determination of blood gas tensions will require the use of an indwelling catheter. Considerable work has already been accomplished in this field and acceptable silastic rubber-tipped catheters exist for this purpose. They are non-thrombogenic and effective. Membrane technology for maintaining a blood gas interface is currently a limiting factor. Currently available models are somewhat large in size and are excessively expensive. They do not permit measurement of pH. Furthermore, they obviate the clinician's ability to measure vascular pressures because these, too, are commonly obtained through indwelling catheters.

A new method of measuring blood or tissue pH is required. Clinical acceptance of a non-invasive blood pressure device must be achieved. Alternatively, a double lumen catheter should be designed, one lumen of which will be closed and under hard vacuum for gas tension measurements, while the other is open and available for standard vascular pressure measurement.

Any catheter chosen must be compatible with the NASA mass spectrometer. It must be inexpensive, safe, and reliable.

It should be possible to place this catheter percutaneously into a peripheral artery through the lumen of an eighteen gauge needle. The catheter should be reusable and constructed of such materials that it can be left in place safely and without altered accuracy for periods of up to one week. Although considerable progress has been made in this area by industrial firms, the development of such catheter technology is essential for a meaningful technology transfer to civilian medicine

APPENDIX I

Error Correction Procedures in Respiratory Calculations

As a first approximation, compliance is the average of each inspiratory tidal volume divided by its associated pressure difference. (See notes on dynamic compliance below.) The elastic work of inspiration is obtained by dividing the integral of the product of flow times the integral of flow, by the compliance.

The nonelastic work of inspiration is obtained by subtracting the elastic work of inspiration from the total work of inspiration. Since the nonelastic work also equals the nonelastic resistance times the integral of the square of flow, the nonelastic resistance may be found by dividing the previously obtained non-elastic work by the integral of the square of flow.

The measurement of compliance and resistance, as described above, can be refined. The computation described above derives compliance by dividing tidal volume by end-inspiratory pressure, which is taken as the pressure at the time of zero-crossing from inspiration to expiration. This gives "dynamic compliance," which is useful but which contains elements of nonelastic resistance and so may differ from the true steady-state compliance (static compliance) by as much as thirty to forty percent if the airway resistance is high. A close approximation can be obtained when an Engstrom respirator is being used. This respirator is designed to maintain a constant inspiratory volume for the moment at the end of inspiration to allow for pressure equilibrium in the lung, so that a compliance calculated from the tidal volume and the airway pressure several milliseconds before the zero-crossing of flow gives a value that in most patients, is close to the true static value.

Another close approximation to true static compliance and true nonelastic resistance can be achieved by using a least-squares fit technique with one of the classical lung-compliance equations to compute compliance and resistance.

The equation used is as follows:

$$P = \frac{1}{C} \int f dt + R \dot{V} + K$$

where p is the pressure (cm H_2O), C is the compliance (liters/cm H_2O), \dot{V} is the flow (liters/sec), R is the nonelastic resistance (cm H_2O /liter sec), and K is the constant of integration (cm H_2O).

Pressure and flow signals are collected during inspiration. The volume at each point during the inspiration is found by integrating the flow up to that time. These parameters are then placed in two matrices representing the coefficients of the above equation and the least-squares fit is performed. Thus we solve for the lung compliance and nonelastic resistance simultaneously.

The calculation of respiratory gas quantities is complicated by the fact that although flow is sensed more or less instantaneously, approximately one-half second lag is involved before the corresponding gas sample can be pumped through approximately twelve feet of tubing to the gas analyzers. This lag is determined by computer by comparing the start of inspiration with the drop toward zero of the CO_2 concentration. Flow values are then stored for this lag period before being multiplied by the corresponding oxygen and carbon dioxide concentrations.

A comment may be in order about the special technique of adjusting measured tidal volumes for the purpose of determining oxygen uptake. Errors are reported due to temperature change (for a $10^\circ C$ temperature rise the measured expired volume will exceed the inspired by 1.7 percent due to expansion and an additional 0.75 percent due to increased viscosity), gas composition (if air is inspired and 5 percent CO_2 expired, the expired volume will measure 1.4 percent low due to decreased viscosity), pressure (if inspiration is 20 mm Hg and expiration at atmospheric pressure, expiration will measure 2.6 percent greater due to expansion), and respiratory quotient (RQ). The cumulative effect of these is about 5 to 7 percent on tidal-volume measurement. However, a serious multiplication of error may occur in determining oxygen uptake at high concentrations. For example, if a patient inspires 60 percent O_2 and expires 57 percent O_2 , a 1 percent error in tidal volume will cause a 20 percent error in oxygen uptake. For illustration, if tidal volume is 1,000 cc, the oxygen uptake should be 30 cc per breath, the difference between 600 cc O_2 inspired and

570 cc O₂ expired. If, however, the expired volume is measured as 1,010 cc, the computed expired O₂ will be 575.7 cc, giving an uptake of only 24.3 cc per breath. These errors are minimized by a two-step correction. The first step, which corrects for all errors, assuming unity RQ, consists merely of multiplying the inspired oxygen volume by the ratio of expired to inspired tidal volume. The second step is a reiteration using the corrected value. For example, consider first the effect of temperature alone. The measured inspired and expired volumes should be equal except for the volume-expansion and viscosity effects. Even if the air-stream temperature were measured, it would be difficult to make the proper correction because of uncertainty as to the heat-exchange effect of the pneumotachograph. However, the proper temperature correction would be that which just canceled out the tidal-volume imbalance, which is precisely what the above multiplication does. The adjustment is made to be consistent with expiration so that final uptake figures will be expressed for body temperature. The same argument may be seen to correct for changes in viscosity due to changes in composition of the gas, provided the respiratory quotient is unity.

The pressure effect automatically cancels out, since the oxygen cell measures partial pressure of O₂ rather than percentage composition. Thus if the pressure were doubled, the flow measurement would be halved, but the partial pressure would also be doubled, giving the same indication of quantity of oxygen passing through the pneumotachograph.

Humidity is not a problem, since the respiratory gas is saturated at both inspiration and expiration .

In summary, the first step of the correction assumes that if the RQ were one, inspired and expired volumes would be equal when adjusted for temperature, pressure and concentration viscosity effects.

$$V_I^2 = V_I O_2^c \times \frac{V_E^m}{V_I^m} \quad (1)$$

In eq. (1) and the subsequent calculations, the following notation is used: V_I and V_E are the inspired and expired volumes, respectively; O_2 and CO_2 represent oxygen and carbon dioxide, respectively, superscript m designates a value computed directly from a primary signal (initial measurement); superscript c designates a value first computed from an m value; superscripts 1, 2, and 3 indicate progressive calculations; and V_{O_2} is the oxygen uptake.

As a second step, the oxygen uptake is recalculated on the basis of volumetric alterations produced by the first step:

$$V_{O_2}^2 = V_I O_2^2 - V_E O_2^c \quad (2)$$

($V_{O_2}^1$) is not used).

Carbon dioxide production is calculated directly from the observed $V_E CO_2$, since no CO_2 is supplied during inspiration by the patient.

A new inspired volume, now adjusted for RQ , is calculated by subtracting oxygen uptake from, and adding CO_2 production to, the measured inspired volume:

$$V_I^2 = V_I^m - V_{O_2}^2 + V_E CO_2^c \quad (3)$$

The originally calculated inspired oxygen is now multiplied by the ratio of expired tidal volume to the new adjusted inspired oxygen volume:

$$V_I O_2^3 = V_I O_2^c \times \frac{V_E^m}{V_I^2} \quad (4)$$

A new oxygen uptake is calculated:

$$V_{O_2}^3 = V_I O_2^3 - V_E O_2^c$$

This procedure could be reiterated, but in practice a single series of calculations is adequate. The error correction procedure breaks down if pure oxygen is inspired.

The correction also tends to correct for leaks, which are troublesome with face masks, although not usually with endotracheal tubes or tracheostomies. However, if the tidal-volume imbalance exceeds ten percent the measurements are doubtful and the equipment should be corrected.

APPENDIX J

The NASA Integrated Medical and Behavioral Laboratory Measurement System (IMBLMS)

For the past few years NASA has been developing IMBLMS to perform medical research during extended manned space flights. The general scope of the IMBLMS program is described in Reference 37.

As part of the studies of the Ad Hoc Group on Pulmonary Care, the IMBLMS program was reviewed to determine if those parts of the IMBLMS package related to respiration and pulmonary function might be applicable to civilian respiratory care.

There are many pulmonary function testing systems available from commercial suppliers, and a basic question to the Group was whether or not the IMBLMS would offer any substantial improvement other than its reduced size and high reliability. The tests and measurements to be performed by the IMBLMS are outlined below

<u>Checklist of IMBLMS measurements pertinent to RICU</u>	
Respiratory rate (from flowmeter or spirometer)	x
Vital capacity	x
Timed vital capacity	
Inspiratory capacity	
Expiratory reserve	
Tidal volume	x
Minute ventilation	x
Maximum inspiratory, expiratory flows	
Alveolar pCO ₂ , pCO ₂	x
Respiratory dead space	x
Alveolar ventilation	
Residual volume	
Airway resistance	x
Compliance	x
Cardiac output	—
Oxygen consumption, CO ₂ production	x
Lung diffusing capacity	

The system is designed around three basic elements:

1. Mass spectrometer for the gas measurements. Particular attention is being directed at the Perkin Elmer unit which is discussed elsewhere in this report.
2. Spirometry. A positive displacement spirometer (rolling diaphragm type) is being used. An accurate flowmeter with an integrating circuit would be desirable to replace the bulky spirometer. NASA has studied this problem at great length but is discouraged by the current state-of-the-art in flow meters as a replacement for a spirometer. Respiratory flow meters are discussed in Section 2.1.2.
3. Data management. Three levels of computers are being developed by NASA to handle the basic data compilation and processing, numerical computation, and control. First are local logic circuits which do little more than handle data print-out. Second, pre-processing is performed in a moderately-sized remotely-located computer which does most of the computation except the most complex. This machine handles most of the control functions. Third, for the most complex computations and operations a large ground-based computer is used.

The current pulmonary segment of the IMBLMS breadboard unit works, and is in use in routine physical exams in the NASA screening program. The next step is the development of a ground-based flight unit (engineering development unit phase). If this appears useful, extra units may be built for principal investigators in the civilian sector.

Dr. Sam Pool of the Medical Research & Operation Directorate-NASA, urged that the pulmonary Ad Hoc Group bear in mind that the IMBLMS program has been set up primarily as a research unit. Many of the developments would not be useful if

they were transplanted directly into a clinical situation. Commercially available pulmonary function testing units do not have the mobility, reliability, compactness and ease of use that are needed at the bedside of an RICU, but it is likely that some of the IMBLMS development may be useful for these purposes.

APPENDIX K

Engineering Specifications for a Respiratory Flow Meter

First, it is important to specify the type of application envisioned for the flow meter. If the device is to be used only for intensive care monitoring purposes, with patients either on or off a respirator, the maximum flows to be expected will be approximately one-half those encountered in pulmonary function testing. On the other hand, in pulmonary function testing, the lower velocity limit is not critical, because the subjects can be instructed on appropriate breathing patterns. For the time being it may be reasonable to allow for both, with the possibility that one flow meter will serve many different functions.

The maximum expiratory flow rate which can be achieved by normal subjects (this would be equivalent to the airway velocity of a cough or a sneeze) is of the order of eight liters per second. Translated into linear velocity through a 1" diameter tube, this would correspond to a peak velocity of approximately 50 feet per second or 1,600 centimeters per second. For the bedside monitoring application, therefore, one could cut the upper end at about 25 feet per second.

For the lower limit, optimally one would like to measure velocities as low as 1 centimeter per second. For the bedside application it is probably essential to go this low. Again, for the pulmonary function testing case, one could allow a higher lower limit.

The output of this flow meter should be in a form which can be processed to yield certain specific pieces of information: first, instantaneous flow rate (liters per second); second, tidal volume; and finally minute volume (liters per minute). The computational equipment necessary need not at this time be considered as part of the flow meter itself; however, the computations will unavoidably place certain constraints upon the flow meter performance.

From the engineering standpoint, the specifications may be summarized as follows:

1. Resolution: five cc per second (equivalent to one centimeter per second velocity through a one-inch diameter throat). The throat may be somewhat constricted for a short distance in order to obtain higher measurable velocities. For an adult-sized flow meter the throat diameter should under no circumstances be less than one centimeter.
2. Dynamic range: 1,000 for bedside application, 2,000 for pulmonary function testing.
3. Frequency response:
 - Optimum: DC to 25-30 cycles per second
 - Acceptable: DC to 20 cycles per second.
4. Linearity:
 - Optimum. 0.1% of full scale.
 - Acceptable: 1% of full scale.

(By rough calculation, a one percent error in the measurement of either inspired or expired volume will give a five percent error in oxygen consumption which, for most purposes, would be acceptable. However, that 5 percent estimate neglects other sources of error, so anything which can be done to clean up the data is desirable.
5. Changes in gas composition: Ideally, the flow meter would have built-in compensation for variation in gas composition. As a practical, and possibly essential, alternative, it must be possible to demonstrate, that with an adequate gas analysis system, such compensation can be made by calculation. Normally, the subject will extract approximately four percent (by volume)

of the oxygen in the inspired air, and will produce approximately 4 percent CO₂ in the expired air. A patient will be breathing oxygen concentrations ranging from 21 percent to 100 percent. The expired air will leave the patient's airway 100 percent saturated with moisture at body temperature; in some cases there may even be some moisture particles entrained in the inspired air. As the expired air cools, moving through the various types of tubing apparatus, we may expect the air to be supersaturated and contain a fair amount of mist.

From the practical standpoint, several additional considerations should be included in the specifications of the flow meter.

1. The performance of the flow meter should not be too sensitive to accumulated moisture. It should be easy to clean and dry out, and it must not be fragile. Frequently sputum and bloody mucous as well as water will appear in the expired air line, and this must be cleaned out from time to time. Therefore, the transducer should be one which is easily wiped clean by insertion of swabs and can be rinsed. It will undoubtedly be dropped from time to time.
2. It is foreseen that the transducer, if not actually used in the operating room, will be employed with patients whose inspired gas mixture will contain a finite level of an explosive anesthetic. Therefore, the entire transducer system in contact with the respiratory gases should be explosion-proof.

APPENDIX L

Ultrasonic Flow Meter Development

The two instruments described here are the Statham Instruments' device and the NASA development from the Electronics Research Center.

On the Statham meter, some technical information is available. The product is a result of a six year in-house program which has suffered from occasional key personnel turnovers. Production models are now available. The transducers used in the evaluation models were made in-house, but production ones will be made outside. Projected price is \$1,500 for a model which simply gives an analog output of flow velocity and \$3,000 for one with additional readout of respiration rate and tidal or minute volume. Essentially all of the circuitry is analog.

Maximum full scale flow rate accepted is 120 L/min with possible extension to 240L/min; the pulse rate is 100 kHz. Linearity claimed is within ± 1 percent full scale and overall accuracy is within ± 5 percent for unspecified conditions. Indicated flow rate is evidently not sensitive to barometric pressure.

The O_2 control knob adjusts sensitivity; variation in the reading between twenty percent O_2 and 100 percent O_2 is about 16 percent if the control is not readjusted. No data is available on effects of other gases such as CO_2 , Halothane, etc. Other controls are provided for calibration and for adjusting response to bidirectional flow.

The instrument is for patient monitoring, but other more demanding applications are envisioned. While it appears to hold an advantage over the Fleisch Pneumotachograph, it is not presently viewed as the panacea for all respiratory flow measurement. Sensitivities to gas composition and artifacts on baseline due to moisture still elude the design.

The status of the NASA/ERC device is less detailed. The design effort to date has not demonstrated practical feasibility, i. e., no measurement data have been taken. The basic approach appears valid, however, and worthy of further research and development for specific product generation. Merits of the technique, once perfected, are high resolution of flow in non-particulate fluids, relative insensitivity to changes of fluid composition and temperature, and elimination of obstructions in the flow field. Substantial improvements in the reliability of measurements are expected when compared with pressure drop methods (the pneumotachograph), thermal techniques (hot-wire anemometry), and rotametric devices (e.g. the Wright respirometer).

The problems encountered in the design of such an instrument can be located within three general areas:

1. Adequate mathematical modeling of the appropriate phenomena and manipulation of these models to determine suitable design criteria, and critical parameters.
2. Design and implementation of hardware to realize the algorithms elucidated from the developed model.
3. Hardware difficulties not necessarily related to the adequacy of the model, e. g. procurement of transducers meeting the requirements of the model, noise encountered in real processing systems, buildup of component tolerances, subtle component failures.

On the basis of the above problem areas, further development is recommended and would consist of:

1. A complete examination of the principles to develop a useful mathematical model. The model should be flexible enough to include the effects to be exploited in the measurement device and also the major disturbances and influences which would corrupt the data (and thus give information concerning feasibility of correcting such data).

Manipulation of a carefully developed mathematical model should provide preferred design criteria regarding transducer selection (or design), mounting geometry, modulation format, and signal processing algorithms. A computer simulation is anticipated, using facilities already in operation at the University of Virginia, for example. The simulation study makes it relatively easy to perform parametric studies which would be either difficult, impractical, or impossible with a specific hardware device based on a necessarily incomplete model.

Development of signal processing algorithms and adequacy testing by variation of flow profiles and symmetry as well as gas composition will be greatly facilitated by the use of pre-hardware simulation. Obviously these studies are necessary to obtain an instrument design optimized for cost, resolution and accuracy. The model, once proven for the general case, can be used to generate design criteria for applications with similar but different requirements, e.g. measurement of fluid speed in physiological systems, aircraft, high-speed ground transportation, underwater vehicles and process control.

2. Design, construction, test and evaluation of a deliverable hardware version of the instrument as modeled and as based on the insight obtained in the analytical phase of the study. In addition to the hardware, a complete documentation package containing all information relevant to development and implementation of the model would need to be provided.

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FINAL REPORT
OF THE
CARDIOVASCULAR CARE AD HOC GROUP
TO THE
SUBCOMMITTEE ON TECHNOLOGY AND SYSTEMS TRANSFER

Committee on the Interplay of Engineering
with Biology and Medicine

NATIONAL ACADEMY OF ENGINEERING
Washington, D. C.

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FOREWORD

The National Academy of Engineering, in its role as an advisor to Congress and Federal agencies, has placed responsibility for studies of the engineering-medicine interface within its Committee on the Interplay of Engineering with Biology and Medicine. Under this Committee is a Subcommittee on Technology and Systems Transfer which is concerned with the transfer of technology and expertise from within Federal agencies (e.g. NASA) to the public sector of health care delivery.

Under this Subcommittee three AD HOC GROUPS of engineering and medical experts were formed in the following areas: Cardiovascular Care, Pulmonary Care and Remote Diagnosis and Treatment. Each group was presented with the following charge:

1. EVOLVE a statement of medical problems within the specialty of each GROUP as they pertain to the DELIVERY OF HEALTH CARE. Such a statement should rank problems in order of importance as based upon appropriate criteria which shall include (a) number of persons affected, and (b) potential for solution within one to five years.
2. EVALUATE current projects and technology within NASA and other agencies which could have a high impact on the problems so delineated. The desired output is a judgment as to which NASA developments can contribute and are apparently ready for evaluation in a clinical setting. Those that hold potential but require further work (modified specifications, re-engineering to reduce cost, etc.) should be so specified to the greatest detail practical for such a GROUP to consider.

Recommendations are desired to a degree of specificity which could normally be anticipated as the outcome of two or several meetings during the next few months.

The work outlined above will assist but cannot, by itself, provide substantive transfer. Because the Subcommittee is

is dedicated to acting as a catalyst in the PROCESS of technology transfer, it is hoped that members of the AD HOC GROUPS would also

3. SUGGEST specific means by which the PROCESS of transfer can begin; for example, evaluation of items in specific clinics and hospitals, further development as required within specified laboratories, establishment of administrative relations between NASA and specific agencies in the health care sector.

The Cardiovascular Care Ad Hoc Group has sought to fulfill its charge through meetings, visits to relevant offices in government, and consulting expert sources of relevant information. While the analysis of major medical problems are the individual efforts of Group members, the whole report has been reviewed and approved by the Group as a whole.

It is realized that many of the recommendations depart radically from previous modes of operation within government organizations. It is felt that this departure is necessary in order to deal realistically with the problem of applying technological skills to the improvement of health care. Because of (a) the complexity of the medical problems, and (b) the inadequate system of specifying health care objectives, technology transfer is particularly difficult. The Group feels it is unrealistic to anticipate that major improvements in health care through technology transfer can be successful in less than five years.

The Ad Hoc Group earnestly encourages the Subcommittee to work with the relevant government agencies in order to affect a change in policies that would permit the successful initiation of the programs suggested herein.

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RECOMMENDATIONS

Recommendations are divided into two parts. The first arose from general discussions about improved health care and contains recommendations which relate to a broad range of medical problems. As such, the potential impact on improved health care is great indeed. Although it is more properly within the purview of the Subcommittee to address such general needs, this Group felt compelled to support these general recommendations for technology in health care delivery.

The second part consists of recommendations which evolved from the study of particular cardiovascular disorders. These recommendations are referenced to coincide with the text which follows:

I. Recommendations Generally Applicable to Health Problems of the Cardiovascular System

RECOMMENDATION 1:

We recommend that medical instrumentation be standardized, viz. the AEC Nuclear Instrumentation Module method (Section 2.1).

RECOMMENDATION 2:

We recommend that the technology of quality control and preventive maintenance be transferred to the biomedical community (Section 2.1).

RECOMMENDATION 3:

We recommend that the DOD and NASA transfer their collective technology associated with physiological monitoring of active subjects (Section 2.2).

RECOMMENDATION 4:

We recommend that the current NASA development of a biomedical mass spectrometer be expanded so as to permit evaluation of its applicability to health care (Section 2.3).

RECOMMENDATION 5:

We recommend that the development of the automated blood pressure method of S.W.R.I. and Hoffman-LaRoche be utilized as an archetype technology transfer (Section 2.4).

II. Recommendations with Specific Applicability to Certain Cardiovascular Disorders

RECOMMENDATION 6:

We recommend that the non-invasive instrumentation currently under development in NASA for future space missions be simultaneously evaluated for its utility in the early detection of stroke, myocardial infarcts, and other degenerative cardiovascular diseases (Sections 1.2, 1.3.2, 2.5).

RECOMMENDATION 7:

We recommend that helicopters be evaluated for their utility in the improvement of health care to the urban trauma victim (Sections 1.3.2, 2.6).

1. STATEMENT OF MAJOR PROBLEMS OF CARDIOVASCULAR CARE

1.1 Introduction

Activities in health care can be categorized by function into diagnosis, prevention, treatment, and recovery. Improved health care may sometimes result from improvement in a single functional area, as when early diagnosis permits the use of preventive measures. In other cases conditions will be improved only by fundamental changes in all four activities. As a general rule, health problems of the former type are more amenable to technological solution. However, these "simple" technology applications are often unsuccessful due to socio-political factors such as cost or the lack of medical consensus. Long-term technological applications which involve major changes in more than one kind of health care activity may yield the most profit for a given investment of resources.

The following statement attempts a quite brief description of diagnostic and treatment procedures associated with a number of cardiovascular disease categories. Problems with the existing technique will be noted. A subsequent section will deal with possible technological improvements which could be made.

1.2 Heart Disease and Stroke

The most serious diseases of the cardiovascular system fall within the categories of heart disease and stroke. So great are these problems that they have been the subject of many national studies.^{1,2,3} These two major cardiovascular disorders persist because there is inadequate knowledge about diagnosis, prevention, treatment, and recovery. The etiology of the disease is only beginning to be understood.

Given this state of knowledge, an immediate application of technology does not appear to portend great improvements in health care for those afflicted. However, because of the magnitude of the medical problem, enormous efforts are being directed toward gaining a better knowledge of these vascular diseases. Advances in non-invasive means of monitoring cardiac functions could

provide the required knowledge of appropriate parameters for use in early diagnosis. Once such knowledge is available, technology should be capable of playing a major role in assisting the vast patient population which is afflicted.

In other areas of cardiovascular care, a more immediate application of technology is appropriate. In these areas, the etiology is better known, and there is good evidence that certain technology, if applied today, would improve health care significantly. Two of these areas are presented in the following sections.

1.3 Trauma

There is no need to over-emphasize the importance of trauma in the United States. It is only necessary to refer to the oft-quoted fact that more Americans died each year during the late sixties from auto accidents than from hostile action in Southeast Asia. Nevertheless, the study and treatment of trauma has not been a popular pursuit and has generally been neglected as a fruitful area of research. In an attempt to reverse this situation, the National Institute of General Medical Sciences recently sponsored an International Symposium on Trauma. The proceedings of this meeting represent the best current source of references.⁴ Because primary treatment of trauma victims is commonly related to cardiovascular injury, a study of trauma is included here.

1.3.1 Epidemiology. The total cost of accidents in the U. S. has been estimated at 27 billion dollars. One-half of this is the result of motor vehicle accidents.⁵ In personal terms, the cost of an accident can be catastrophic. For example, the average cost to a family having a member who suffered severe injury or death in an automobile accident exceeds \$10,000.⁶ The total average cost per auto fatality is close to \$90,000.⁷ With regard to overall incidence, it has been estimated that 50 million Americans suffer accidental injuries yearly. Of these, 11 million are disabled and 115,000 are killed. Even these figures are inadequate to convey the true impact of accidental injuries on the American society. The fact that trauma is the leading cause of death in age groups one through thirty-seven years of age indicates that in terms of potential man-years of productivity the loss is incalculable. This is the most important "disease" affecting active members of society.

1.3.2 Diagnostic and Treatment Procedures.

Automobiles account for over half of all accidental deaths. Of the total number of trauma injuries, home accidents account for 4.5 million injuries, public non-motor vehicle accidents for 2.5 million injuries, and work accidents account for 2 million injuries.

In minor injuries, diagnoses usually involve only a careful examination plus an x-ray if necessary. Treatment is quite straightforward and usually involves local care plus immobilization.

Major injuries are complex, not only because of the degree of injury to a single system, but also because multiple systems are usually involved.

The major cranial problem is the diagnosis of a closed head injury with hemorrhage causing increasing intracranial pressure. This requires surgical decompression. Current diagnostic procedures include serial neurologic examinations, skull x-rays, carotid angiography, and most recently transcutaneous ultrasound.

Neck injuries are important because they may involve several critical systems including the spinal cord, the trachea, and the esophagus. Diagnosis involves clinical examination, x-rays, and endoscopy. Most neck injuries are explored to first rule out injuries to the trachea and esophagus. Cervical spine injuries are treated with skeletal traction and, if necessary, decompression.

Chest injuries usually result in impaired breathing. Diagnosis involves examination of the chest, blood gas analysis and x-ray. The important injuries are pulmonary contusion, and pneumo- and hemothorax. Closed thoracotomy is the usual treatment for hemopneumothorax.

Abdominal injuries include trauma to all organs in the abdomen. Diagnosis involves clinical examination which may reveal signs of peritoneal irritation; abdominal paracentesis which may reveal blood, bile, urine, feces, or gastric content, abdominal x-ray which may show free air and celiac angiography which may show disruption or obstruction of major vessels.

Musculoskeletal injuries are diagnosed by clinical examination and x-ray. Treatment involves fixation and immobilization.

In addition to the specific measures mentioned above, general resuscitative measures are widely employed. These measures include support of adequate ventilation, control of hemorrhage, decompression of chest injuries, and blood volume re-expansion. Indices to be monitored ideally would include arterial pressure, central venous pressure, cardiac output, blood gases, and urine output as well as a hemoglobin level, electrolytes, amylase and liver enzymes.

When applied, these measures are generally effective in salvageable cases. The major unsolved clinical problem is pulmonary insufficiency developing in trauma victims following primary treatment.

Although no hard data are available as yet, it appears that delay in treatment is a major factor in suboptimal treatment. The current system of ambulance transportation has been judged inadequate by many observers. The use of helicopters in conjunction with ambulances is currently being attempted in several regions. Data on effectiveness are thus far scarce.

Transportation systems will be less than optimally effective if unaccompanied by improved coordination and communications between and among mobile units and hospitals. The current lack of an organized system for emergency care results frequently in an ambulance proceeding to the wrong hospital, to one that is poorly equipped, or crowded, or does not have on hand the appropriate specialist, e.g., an ophthalmologist for eye injury.

In research and development for improved procedures of providing care to trauma victims, several important trends can be seen:

- (1) Within the overall framework of regional emergency care statewide trauma systems

are developing which include the potential for rapid helicopter transport, priority communications systems, and improved training of surgeons. These systems will include designated trauma centers which should develop a high degree of proficiency in trauma treatment.

- (2) Recognition is growing at the federal level that increased funding to support trauma centers and trauma research is critical.
- (3) The development of improved monitoring devices such as mass spectrometry and ultrasound is underway.

1.4 Peripheral Vascular Disease

There are at present two major disease entities which affect the population of the United States which are of major concern and national importance. These diseases are thrombophlebitis, with or without pulmonary embolism, and arteriosclerosis obliterans. Since the problems posed by these diseases are somewhat different, they will be considered separately.

1.4.1 Arteriosclerosis Obliterans

(a) Epidemiology. The exact incidence is unknown but it does appear to parallel the problem of atherosclerosis in other areas. In 1965 alone, approximately 850,000 people died secondary to the complications of atherosclerosis. There are no exact figures available on the incidence of the disease as it affects the peripheral arteries, but it is certainly as common as its occurrence in the coronary arteries.

The mortality from occlusive arterial disease of the limbs is very low. This is because of the fact that even when gangrene develops the patient's life can be saved by amputation. The major problems that occur secondary to arteriosclerosis obliterans are: (1) reduction in work capacity, (2) pain either with exercise or at rest; and (3) amputation.

There are no figures available to suggest that there is a geographic difference as to incidence and mortality.

Arteriosclerosis obliterans has its highest incidence in the male. The age groups primarily affected are in the forty- to seventy-year age range. Females tend to be about ten years older in this regard. Occlusive arterial disease is approximately three times as common in patients with diabetes mellitus.

(b) Diagnosis and treatment procedures. The etiology of the disease is poorly understood. It is probably related to many factors such as genetic background, lipid abnormalities, hypertension, and physical factors. The exact role of each of these factors remains obscure.

Even in the best U. S. medical facilities, the diagnostic procedures still revolve around clinical evaluation and arteriography. While there is increasing interest in other methods of study, these are used only on a limited basis in relatively few centers.

Effectiveness of diagnostic procedures is limited. By the time the patient develops symptoms or signs, the diagnosis is relatively easy to make. The arteriogram is used to precisely localize the site of involvement and determine whether or not the lesion is amenable to surgery.

The problem with the clinical evaluation alone is that it is relatively insensitive and cannot detect subtle changes that occur in the disease process. Arteriography, while very helpful, cannot be applied as frequently as desired due to cost and the potential risk to the patient of arterial catheterization.

The therapy for this problem is largely surgical but is applicable to only about 5 percent of patients so afflicted. Other therapeutic practices include keeping the feet warm.

Direct arterial surgery will relieve the symptoms of claudication in approximately 90 percent of the patients in whom it can be applied. It is not without risks, however, some of which are as follows: (1) mortality - 1 to 3 percent, (2) immediate failure of procedure - 2 to 5 percent; (3) limb loss - 1 to 2 percent, and (4) long-term complications such as embolism, false aneurysms and infections.

At the present time arteriography is widely applied in the United States for the evaluation of peripheral arterial disease. The great need at the moment is to develop and make available newer physiologic methods of evaluation. The factors that have to date limited the development and acceptance of the newer techniques are: (1) cost; (2) complexity; (3) requirement of technical personnel, (4) time for performance of test; and (5) a general reluctance to accept the value of such testing. This last factor is without a doubt the greatest hindrance to more widespread acceptance of newer methods of diagnosis and evaluation.

1.4.2 Thrombophlebitis

(a) Epidemiology. The incidence of thrombophlebitis is unknown but extremely common, particularly in the hospital setting. It has been estimated that pulmonary embolisms secondary to thrombophlebitis account for approximately 10 percent of in-hospital deaths.

There are no good national mortality figures. There appears to be no relationship between incidence and geography.

The disease affects all ages but is most common in patients with trauma and the chronically ill.

While there is a much higher incidence in the chronically ill patient, it frequently affects the young, healthy person who is forced into the hospital for a variety of reasons. There are two major aspects of this problem on the national level. These are the mortality that occurs with pulmonary embolism and the long-term consequences when the disease passes into the chronic phase (the post-phlebotic syndrome). It has been estimated that when the post-phlebotic syndrome develops, the average annual hospital stay is on the order of thirty days. It should be emphasized that the number of such patients is probably in the hundreds of thousands.

(b) Diagnostic and treatment procedures. The etiology of the disease remains obscure. About all that is known is that the process is in some way related to chronic illness and bed rest.

The current diagnostic procedure used in the best centers consists primarily of venography. This method is very accurate in making the diagnosis when symptoms appear, which is late. It is also rather difficult to satisfactorily visualize the entire deep system of both legs up to the level of the inferior vena cava. The major problems with venography are cost, time required, need for highly trained physicians, and the relative infrequency with which the tests can be repeated.

Diagnosis is accurate when venography is employed. Treatment with Heparin in the acute phase is helpful but there are a significant number of failures. The recent re-introduction of newer fibrinolytic agents does offer some hope for the future.

The failure to use venography more widely is simply a problem in the education of physicians.

The current research and development have concentrated on newer diagnostic methods which might permit an earlier diagnosis (before symptoms develop) so that clot propagation and in some instances pulmonary emboli can be prevented. The efforts which hold the greatest promise are as follows.

(1) continuous wave ultrasound for the ileo-femoral and femoral popliteal area; (2) impedance or strain gauge plethysmography for the calf region; and (3) isotope uptake methods for the calf. The studies reported to date are promising.

The evidence that early diagnosis will result in more effective therapy is at present lacking. However, the disease is detected at relatively late stages at the present time. It is generally assumed that the earlier the diagnosis can be made, the more effective the therapy will be for this disease. Early institution of anticoagulant treatment should, for example, drastically influence the natural course of thrombophlebitis.

2. STATEMENT OF PROPOSED APPLICATIONS OF TECHNOLOGY

Several recommendations for the use of technological hardware and technique in improving cardiovascular care have arisen from general discussion of needs and desires in cardiovascular care. Other application programs have their basis in specific inquiries of the kind performed above. These two separate types of recommendations are reviewed here.

2.1 Reliable and Standardized Cardiovascular Instrumentation

There are enormous benefits to be gained from the establishment of certain standards with regard to cardiovascular instrumentation. Units purchased from different manufacturers would be interchangeable. Technician retraining with new instruments would be minimal. Reliability and servicing would be enhanced. While the method has been successfully utilized by the AEC in the Nuclear Instrument Modules, the establishment of such an activity in the more diversified biomedical field will be enormously more difficult. Yet, its intrinsic value to the improvement of health care has led the Group to recommend that the Federal agencies lead in the evaluation of such standardizations. In addition to the experience of the AEC, the biomedical expertise within HEW, and the need and purchasing power of DOD, there must be the ability to successfully carry out this vital technological development.

Standardization implies enhanced reliability as well as uniformity. There have been too many incidents in the medical community caused by operating under the strain of unreliable instruments and spiraling service costs. Education in the area of quality control (QC) and preventive maintenance (PM) is needed by hospital technologists and equipment designers alike. Even though hospitals are not built with the same systems approach that a spacecraft is, Federal agencies like NASA, AEC, and the DOD are the repositories of QC and PM technology and, as such, should be encouraged to disseminate this competence to a biomedical community that is, as yet, only slightly aware that it even needs this technology.

2.2 Stress Testing

In the field of cardiovascular disease diagnosis and prevention, there is a general need for new approaches in screening large numbers of individuals on a regular basis. Stress testing as a means of mass screening for cardiovascular disease is rapidly becoming a preferred methodology in the hands of those centers where such capability exists. NASA and DOD have extensive experience in the physiological monitoring of healthy personnel undergoing physical exercise. This instrumentation and analysis technology should be evaluated for its utility in increasing the use of stress testing.

2.3 Mass Spectrometry

Another general area of technological need is that of the continuous measurement of blood gases for very ill patients. The mass spectrometer under development by NASA's Johnson Space Center in Houston has applicability to the problem of continuously monitoring arterial blood gases in ICU/CCU patients due to its potentially high reliability and small size. Although the device is still only under development, the current medical need is so clearly documented that now is the time to begin development of an instrumentation system. (See Report of Pulmonary Care Ad Hoc Group.) It is also felt that parallel evolution of a medical application of the device could result in a savings of long-term development costs for both NASA and the biomedical community. Because of the novelty of the concept of parallel development of systems for space and medicine, the parent Committee is urged to consider this concept more thoroughly.

2.4 The Technology Transfer Process

Finally, the Cardiovascular Care Ad Hoc Group recognizes that the objective of technology transfer from aerospace to medical application is a difficult process, fraught with potential bottlenecks and layers of bureaucratic resistance. Presumably the process must involve not only one or more government agencies but also extensive redesign by some unidentified party, clinical trials, and ultimately industrial production and sale. Throughout this period, some one individual or group must be willing to sponsor the transfer in the sense of shepherding it through all the required elements.

While each device or technique which has thus far succeeded in being so transferred undoubtedly has a unique history, there are probably some historical events common to them all, the study of which could benefit a group like the Subcommittee in its assigned task. For that reason the Ad Hoc Group would commend to the Subcommittee's attention the historical development of one particular medical device which is known to the Group and has potential for making an important contribution to health care. That device is the automated blood pressure machine of the Southwest Research Institute and Hoffman-LaRoche Co. This device was first developed for a government aerospace application; it has now undergone the complete transformation to an industrial product for clinical use, including re-design, cost analysis, and clinical trials. A bibliography of its development and transfer is included in Appendix A.

2.5 Disease-Related Technological Needs: Non-invasive Instrumentation

In Section 1.2 above, the potential for non-invasive bioinstrumentation to help in the study and early detection of stroke, myocardial infarcts, and other degenerative cardiovascular disease is noted. Activities at NASA Ames Research Center into non-invasive means of monitoring cardiac functions such as left ventricular stroke volume seem to parallel the requirements of current clinical trials for cardiovascular disease. These trials involve invasive means at present and, if successful, will indicate the appropriate parameters of cardiovascular performance that are needed to provide an early diagnosis of cardiovascular disease. Admittedly, there are several university bio-engineering teams actively developing non-invasive methods of cardiac evaluation (especially University of Washington, Northwestern). But, there is need for a much greater engineering effort if the instrumentation is to be available when the clinical trials are complete.

The need for such instrumentation is also suggested by a study of current procedures in trauma cases (see Section 1.3 above).

NASA Field Centers with their extensive experience in instrumentation development, would undertake a parallel instrument development for mass screening applications if: (1) they were

given a mandate from Headquarters, and (2) a strong link with a clinical research group(s) could be established. This activity would be an example of "planned technology transfer" that should assure a more successful transfer. It would also be useful to NASA, for their contractors would see a broader market for their development, which should encourage a reduction in price. It is recognized that the clinical research team would have to seek alternative sources of support for their trials, but this should be easier if the granting agency knows that bio-engineering support will come from NASA. Recognizing that such programs would require extensive liaison between NASA and another granting agency (public or private), this Group would recommend that the NAE consider adapting this liaison role in order to test the feasibility of this type of development activity.

Considerable technological research and development is underway in the peripheral vascular field. This was in large part stimulated by the development of transcutaneous ultrasonic techniques. These methods, although at present qualitative, indicated the feasibility of obtaining useful physiologic data through the skin at several levels of the limb. The present efforts involve a combination of (1) basic engineering efforts to improve currently available instrumentation; (2) a more intense look at fluid mechanics and wall properties analytically, and (3) an attempt to quantitate many of the variables such as volume flow, pulse wave transmission and compliance. The major research efforts have included such items as ultrasound, both pulsed and continuous wave; electromagnetic flowmeters, either periarterial or catheter tip; thermography; dye-dilution methods; isotype clearance, and plethysmography.

Up until a few years ago, there was very little evidence that early diagnosis would be helpful in treatment. There is now a faint glimmer of hope as evidenced by the fact that lipid disorders can be classified more accurately. This suggests that by more complete categorization it may be possible to study the effects of therapy in a more intelligent setting. For example, there is evidence that treatment of the type III hyperlipoproteinemia will result in measurable changes in the peripheral circulation.

There are several compelling reasons why early diagnosis should be one of the major goals in this area. These are as follows. (1) technologically it looks feasible at the present

time and within a reasonable amount of time; (2) the peripheral arteries are accessible to study in contrast to the vasculature of the heart and brain, (3) the peripheral arteries provide an excellent target area to follow in the field of arteriosclerosis; (4) repetitive testing which is absolutely essential to determine the natural history of the disease is feasible.

2.6 Research into New Transport Systems

The last specific recommendation emerges from consideration of medical procedures related to trauma (Section 1.3.2). Research and development of improved transportation and communications systems appear essential if much improvement in health care is to be afforded trauma victims in the future.

While helicopters are known to be useful in reducing combat mortality and morbidity, there are several reasons why this level of success could not be attained in civilian health care. Several preliminary efforts to utilize helicopters are underway presently. There is no organized effort to evaluate the manner in which this service influences health. Even if the state police can show that the mean time from accident to hospital is reduced with helicopters, the patient may still suffer because of being taken to a poorly equipped hospital (see Appendix B). It is necessary, therefore, to undertake better studies of the health care changes afforded by helicopter services (coupled with good communications). This study should be implemented with existing helicopters before a costly redevelopment of helicopters, communications, and hospitals is undertaken.

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APPENDIX A

DEVELOPMENTAL HISTORY OF AN AUTOMATIC BLOOD PRESSURE
MEASURING DEVICE: THE ARTERIOSONDE

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ROCHE MEDICAL ELECTRONICS DIVISION
HOFFMANN - LA ROCHE INC
CRANBURY, NEW JERSEY 08512

February 12, 1971

609-448-1200

Dr. Richard Buckles
Pharmetrics
2631 Hanover Street
Palo Alto, California 94304

Dear Dr. Buckles:

I am most glad to be able to cooperate with your National Academy of Engineering Committee in supplying you with information about the Arteriosonde, one of the devices that is an outgrowth of some Government biomedical engineering efforts.

As you know, the device concept was first developed and promoted by Dr. Ray Ware at Southwest Research Institute in conjunction with an Air Force contract. A basic patent was issued to Southwest Institute and this patent is now under the control of Roche Medical Electronics Division. I think this patent position may be a significant factor in why this device was developed and marketed by an industrial group.

At first a team of Roche physicians and engineers worked with Southwest Research Institute in developing an early proto-type commercial version. This device went through three more proto-type phases before it was ready for clinical investigation by third party outside investigators. These investigators were chosen to represent a wide spectrum of applications; from screening clinics and research centers, through obstetric wards and anesthesia departments. I am attaching a list of the pertinent investigators with an indication of the type of work each is doing. Feel free to contact any one of these. I am also attaching a list entitled "Arteriosonde Bibliography" which lists the publications now in the literature concerning the Arteriosonde and the technical papers concerning Doppler ultrasound

Dr. Richard Buckles
Palo Alto, California

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--- blood pressure instruments as related to the Arteriosonde development and a list of papers in press and scientific exhibits concerning the Arteriosonde. The papers are first beginning to appear at this time as the machine was first given for clinical investigations at approximately 1 to 1 1/2 years ago. As you can see in the preprint of my paper which should appear in this month's issue of Current Therapeutics Research, the machine has been evaluated at a variety of clinical sites (I might add that this data is not up to date. We now have more cases). These studies were done in "real life" situations and no attempt was made to induce the fine control of a scientific experiment. We were interested in the practicality and usefulness and the accuracy of the machine in the "field" situation.

The exhibit on use of Doppler ultrasound in induced hypotension by Dr. Poppers mentioned in the list of exhibits and papers won first prize in the New York State Anesthesia Society and is being converted into a scientific publication. Essentially it shows that in induced hypotension using ganglionic blocking agents, pressures as low as 40 mmHg can be accurately measured with the Arteriosonde.

Please let me know what other information you need as we would be glad to supply information which is not considered company confidential or which is not considered confidential by the investigator.

Sincerely yours,



Howard M. Hochberg, M.D.
Director, Medical Department

HMH:mac

Encl:

cc - L. Jonas
W. Sharshon

!
ACCURACY OF AN AUTOMATED
ULTRASOUND BLOOD PRESSURE MONITOR

by

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Measurement of blood pressure through use of an ultrasound beam to indicate arterial wall motion under a deflating occlusive cuff originally was proposed by Ware¹ and by Kirby². Now the concept has been expanded to the point of development of an automatic blood pressure system (ABPS*).

Application of this device involves placement of a cuff over the arm in the usual manner and setting of an ultrasound transducer over the brachial artery. The cuff automatically inflates to a level above systolic pressure and deflates at a preset rate. When cuff and systolic pressures equalize, the arterial wall moves and causes a change in the ultrasound field in the arm. This change (Doppler shift) is detected by the system and the reading is confirmed by complex logic. Diastolic pressure is noted at the point of marked diminution in arterial wall motion. Both pressures are displayed on the mercury manometers incorporated into the system.

After extensive evaluation by Roche Medical Electronics, a program of evaluation by experienced clinical investigators was undertaken. Seven studies were carried out at seven teaching hospitals under the supervision of the directors

*ARTERIOSONDE,[®] trademark of Roche Medical Electronics Division, Hoffmann-La Roche, Nutley, New Jersey

of: two departments of obstetrics and gynecology, two departments of anesthesiology, one cardiac catheterization laboratory, one intensive care unit, and one hypertension study unit.

To give the system as severe a test as possible, the patients selected for monitoring were usually those who were severely or precariously ill. Comparisons with Korotkoff as well as intra-arterial methods of blood pressure determination were performed in an aggregate of 299 patients. The combined results obtained from these studies are the subject of this report.

METHODS AND MATERIALS

Study designs incorporated comparisons of the ultrasound system with Korotkoff measurements taken on the same arm at the same time, with Korotkoff measurements performed at different times and on opposite arms, and with intra-arterial catheterization in the aorta and at the origin of the brachial artery.

During the period between January 1969, and December 1970, data from a total of 299 patients were compiled from the various clinical locations utilized in the seven teaching hospitals. The ages of the 172 females and 127 males ranged from 5 months to 97 years; median age was 29 years--somewhat low because of the relatively large number of obstetrical patients in the population. Nevertheless, 26 per cent were over 50 years old, 8.3 per cent were over 65 years of age, and 4 were at least 85 years old. The varied clinical situations by type and number of participants are summarized in Table 1.

Data were keypunched and analyzed statistically by computer. There was wide variability in the blood pressure of these patients, ranging from low hypotensive

through normotensive to high hypertensive; actual values were 64 to 217 mmHg systolic and 44 to 140 mmHg diastolic. The differences between the ABPS and each of the other methods were calculated for each comparison. The distribution of the systolic and diastolic blood pressure differences, the mean differences, the 90th percentile of the differences, and correlation coefficients were tabulated, calculated, and analyzed.

RESULTS

Findings are summarized in Table 2. The 299 patients accounted for a total of 1903 comparisons, 195 in 58 individuals subjected to intra-arterial and ABPS determinations and 1708 in 244 persons measured by Korotkoff and ABPS methods. Some patients were compared to both methods.

Comparison of ABPS and Intra-arterial Catheterization

Agreement between direct catheterization and indirect ultrasound methods of blood pressure determination was excellent. The mean systolic difference between ABPS and intra-arterial measurements was 0.5 mmHg (standard deviation: 7.3 mmHg, correlation coefficient: 0.96). Mean end diastolic pressure difference was 7.6 mmHg (standard

deviation: 5.7 mmHg, correlation coefficient: 0.92).

Even more important than these overall mean differences was the consistency of reliability throughout the pressure range of this patient population. Figure 1 indicates that at no pressure level within the 65 to 133 mmHg systolic range of the patients did the mean difference between the two methods exceed 6 mmHg. Diastolic pressure in the range encountered in this study (45 to 90 mmHg in the series of intra-arterial comparisons) typically measured 5 to 8 mmHg higher with the automatic apparatus. But consistency, or reproducibility, was better with diastolic than with systolic comparisons; with diastolic, the 90th percentile levels of the measurement differences were within ± 5 mmHg, whereas 90 per cent of the comparisons of systolic pressure were within ± 5 to 10 mmHg of the mean difference.

Comparisons of ABPS and Korotkoff Determinations

The mean systolic pressure difference between these two indirect methods of blood pressure determinations was 0.5 mmHg (standard deviation: 7.4 mmHg, correlation coefficient: 0.96). Diastolic pressure (fourth or muffling phase) comparisons produced a mean difference of 0.1 mmHg (standard deviation: 6.2 mmHg, correlation coefficient: 0.95).

At all pressure levels throughout the range encountered in this patient population (systolic: 60 to 217 mmHg and diastolic: 40 to 137 mmHg for the 1708 ABPS vs. Korotkoff comparisons) neither the systolic nor diastolic mean difference exceeded ± 5 mmHg (Figure 2). The 90th percentile levels of agreement extended approximately to 5 to 7 mmHg below and 5 to 15 mmHg above the mean difference. Diastolic pressure comparisons gave evidence of greater convergence than systolic, but reproducibility was excellent for both.

The consistency of these data was maintained at all ages encountered in this study (shown by 10-year increments in Figure 3). At all ages over 15 years, the mean difference (systolic and diastolic) between Korotkoff and ABPS remained within 5 mmHg; in ages below 15 the mean difference was slightly higher, from approximately 5 to 8 mmHg apart.

DISCUSSION

Previous observations repeatedly have demonstrated differences of greater magnitude between Korotkoff and intra-arterial determinations than between those of the ultrasound system versus either of these methods as expressed in these studies. Measurement of systolic pressure

by catheterization most often produces readings 5 to 20 mmHg higher than Korotkoff readings, but various writers have estimated that up to 36 per cent of intra-arterial systolic pressure determinations may be 5 to 20 mmHg lower than those obtained by auscultation^{3,7}. Hence, the variability between the two traditional methods is indeed high for determination of systolic blood pressure. ABPS determinations of systolic pressure, by contrast, correlate well with either method, direct or indirect. The overall mean difference between ABPS and either of the other methods was within 0.5 mmHg systolic; 90 per cent of the total of 1708 comparisons were less than ± 5 to 10 mmHg different from the Korotkoff pressure.

For diastolic pressure, ABPS determinations correlated nicely with estimates via the Korotkoff sounds method--within 0.1 mmHg. Average diastolic difference of ABPS versus intra-arterial method was +7.6 mmHg. But a steady level of consistency was observed here, in that 90 per cent of the comparisons were within ± 8 mmHg of the mean difference. The small yet consistently higher estimation of ABPS as compared to direct measurement is typical of findings with occlusive cuff methods^{3,7} and is probably a result of one or more factors, namely the relative difficulty in determining minimal wall motion or minimal blood flow disturbance as well, perhaps, as the possible occurrence of a truly local physiological change in diastolic pressure--

a result of cuff pressure.

At any rate this small difference has not been important from a clinical standpoint. Obviously, most clinical decisions of the past traditionally have been made on the basis of indirectly rather than intra-arterially determined diastolic pressures. Agreement of ABPS with auscultation has been good at all extremes of blood pressure encountered and at all ages. Even greater reproducibility would be desirable in patients of younger age (those usually under 11 or 12 years old); thus, a special pediatric transducer has been developed for use in this population. This will be the subject of future reports.

In general, the distributions or spread of the differences in determinations obtained with the various methods were consistent with those anticipated in light of the several influential operant variables: observer accuracy, respiration, and site of measurement. Estimate differences between observers has been reported to range as high as 5 mmHg under laboratory conditions^{8,9} and up to 12 mmHg under ordinary (clinical or epidemiological) circumstances^{9,10}. Blood pressure variation due to respiration has been shown to be often of a magnitude in the area of 8 to 10 mmHg⁷. The author has confirmed this finding through data obtained by catheterization, in which the

median blood pressure difference due to respiration variation was 10 mmHg¹¹. Use of opposite limbs for duplicate blood pressure readings has produced variations up to 10 mmHg, and the difference between pressures obtained at aortic or brachial sites has varied up to 20 mmHg¹¹.

Hence the variability in determinations elicited when the ultrasound automatic blood pressure system was compared in these studies with more standard methods was well within the biological variability of the human organism. Moreover, there appears to be a closer agreement of ABPS with intra-arterial measurement in respect to systolic pressure estimations than heretofore obtained through use of Korotkoff sounds.

CONCLUSION

The data from patients in whom comparisons were made between Doppler ultrasound blood pressure monitor and Korotkoff sounds or intra-arterial blood pressure measurements have shown that the accuracy of the automatic device is well within the expected bounds of: observer variation, physiological difference between points of measurement, and limitations of occlusive cuff techniques.

SUMMARY

Accuracy of a newly developed automated ultrasound blood pressure system was evaluated separately by seven independent investigators, directors of various departments within seven teaching hospitals. The composite population consisted of 299 patients from 5 months to 97 years of age, 172 females and 127 males.

Blood pressures, which ranged from 60 to 217 mmHg systolic and 40 to 137 mmHg diastolic, were obtained from 103 patients undergoing surgery, from 50 during obstetrical procedures, from 6 in shock, from 35 in cardiopulmonary laboratory, and varied others.

In 195 comparisons with intra-arterially obtained (aorta or brachial artery) in 58 patients, the mean systolic difference between methods was 0.5 mmHg and the mean diastolic difference was 7.6 mmHg. In 1708 comparisons with the Korotkoff sounds method in 244 patients, the mean differences were 0.5 mmHg and 0.1 mmHg, systolic and diastolic respectively.

The average difference in diastolic pressure between the automatic system and intra-arterial catheterization agrees closely with results reported previously for

occlusive cuff method comparisons. Considerably better convergence in systolic pressure determinations was demonstrated for the automatic device than had been anticipated on the basis of published standard Korotkoff method comparisons with direct measurement.

About 90 per cent of all automatic system measurements were within 5 to 10 mmHg of either comparison method. The small differences noted were compatible with inherent variables of intra-observer variation, changes due to respiration, and physiologic difference between limbs.

REPRODUCIBILITY OF THE
ORIGINAL PAGE IS POOR

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TABLE 1

Clinical Situations of Patients Monitored
By Automatic Ultrasound Blood Pressure Monitor

<u>Surgery (in operating room)</u>	<u>103</u>	
Neurosurgery		20
Open Heart		8
Hypotensive Anesthesia		5
Hemorrhagic Shock		3
Other		67
<u>Recovery Room</u>	<u>66</u>	
<u>Intensive Care Unit</u>	<u>39</u>	
Monitored Until Death		3
Shock		3
Other		33
<u>OB-GYN Service</u>	<u>50</u>	
Labor/Delivery Room		29
Eclampsia		8
Other		13
<u>Cardiopulmonary Lab.</u>	<u>35</u>	
<u>Not Specified</u>	<u>6</u>	
Total	299	

TABLE 2

Comparison of Blood Pressure Determinations
by Automatic Doppler Ultrasound System with
Korotkoff Pressures Measured on Arm and
Intra-arterial Pressures Measured
in Brachial Artery or Aorta

Method	No. Patients	No. Measures	Systolic B.P.		r	Diastolic B.P.		r
			$\bar{X} \Delta$ mmHg	$\sigma \Delta$ mmHg		$\bar{X} \Delta$ mmHg	$\sigma \Delta$ mmHg	
Ultrasound system vs. Intra-arterial (brachial or aortic)	58	195	-0.5	7.3	0.96	7.6	5.7	0.9
Ultrasound system vs. Korotkoff	244	1708	-0.5	7.4	0.96	-0.1	6.2	0.9

$\bar{X} \Delta$ = Mean of differences in readings.

$\sigma \Delta$ = Standard deviation of differences in readings.

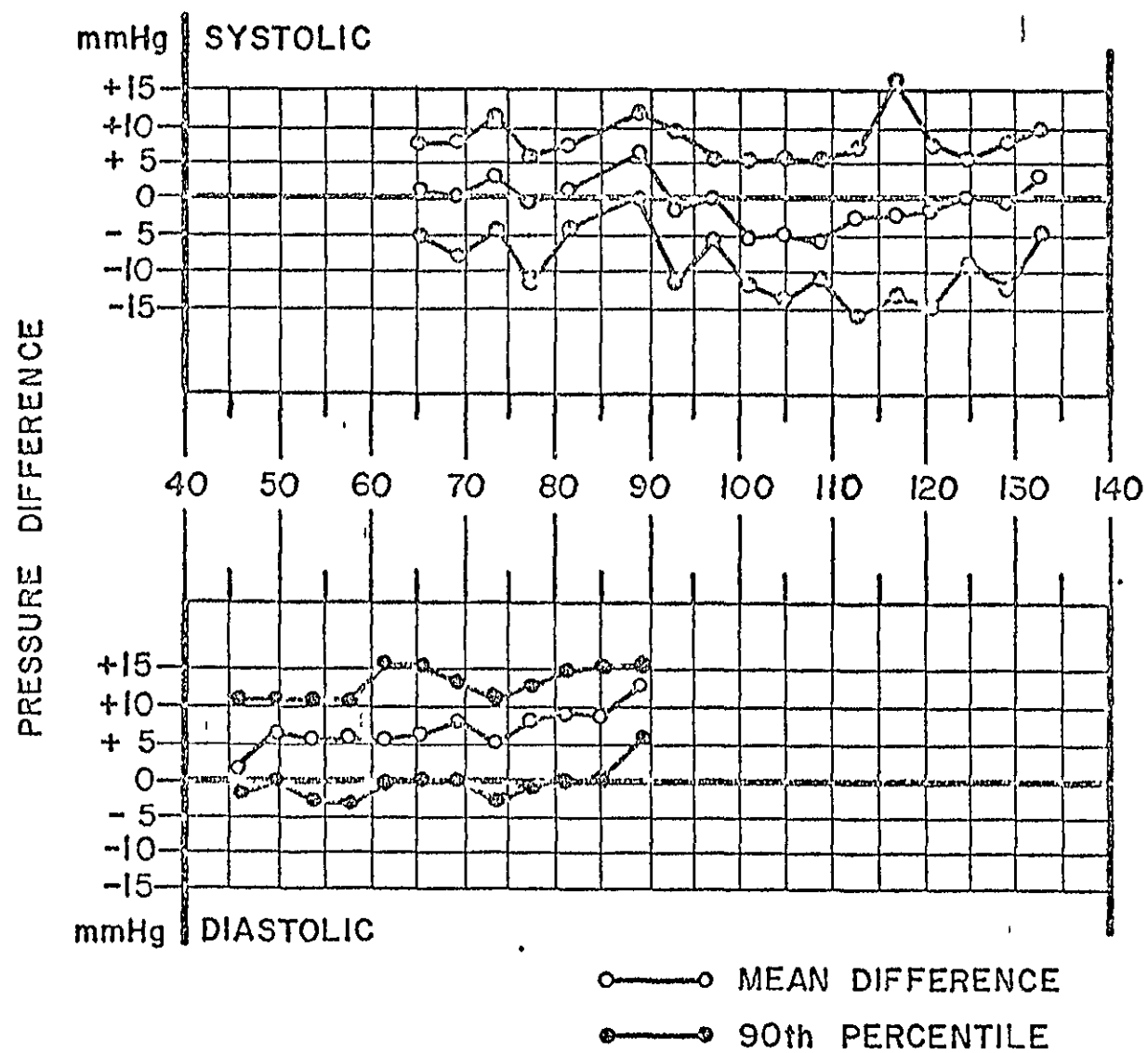
r = Correlation coefficient.

(A negative sign indicates lower reading by ABPS.

Figure 1

Pressure Differences Between ABPS and
Intra-arterial Determinations at Various Pressure Levels.

The mean differences and 90th percentiles of differences of determinations between the intra-arterial standard and the ABPS are plotted for each blood pressure level. Positive differences indicate high readings by the ABPS; negative differences indicate low readings.



PRESSURE DIFFERENCE BETWEEN ABPS AND
INTRA-ARTERIAL

Fig. 1

Figure 2

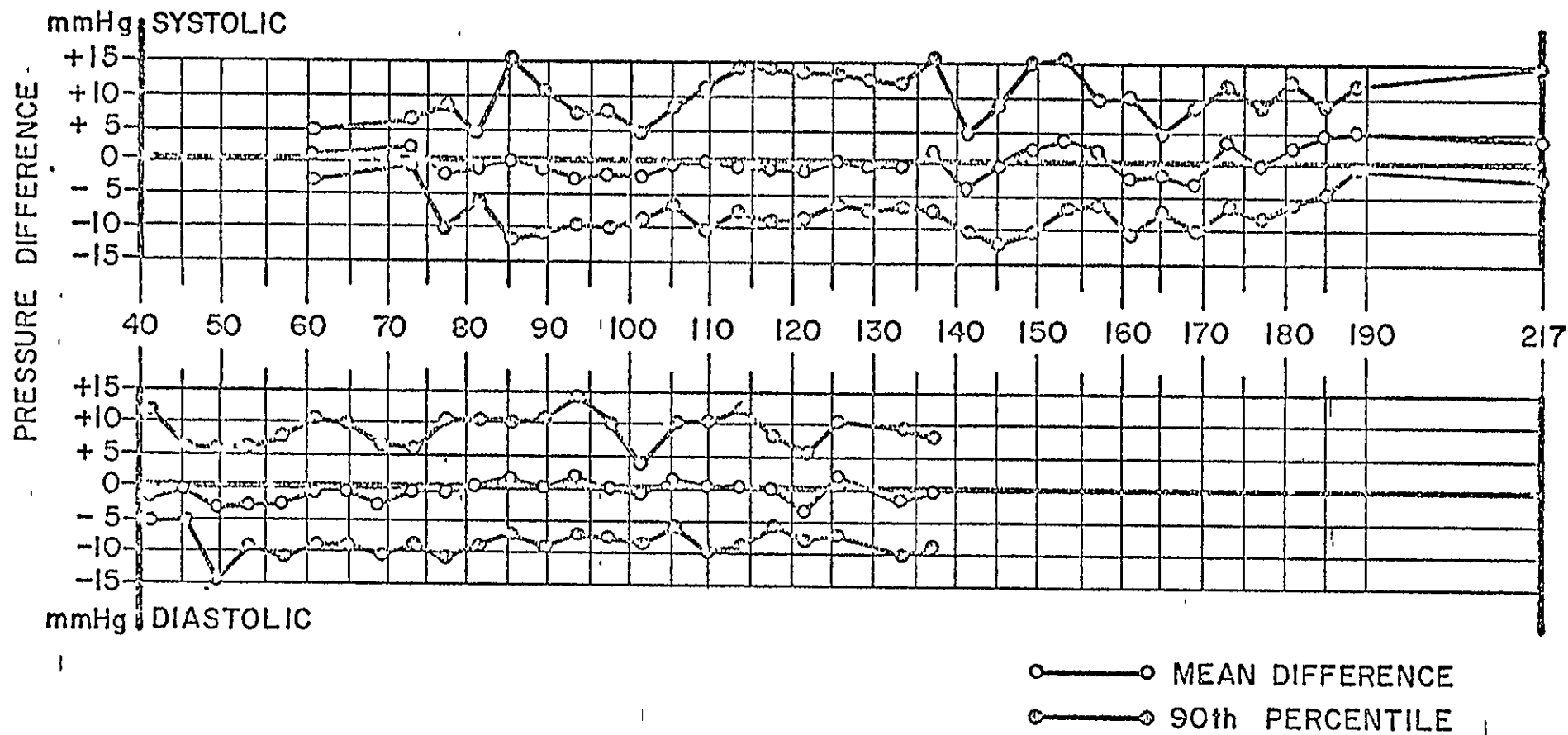
Pressure Differences Between ABPS and Korotkoff Determinations at Various Pressure Levels

The mean differences and 90th percentile of differences of determinations between Korotkoff and the ABPS are plotted for each blood pressure level. Positive differences indicate high readings by the ABPS; negative differences indicate low readings.

Figure 3

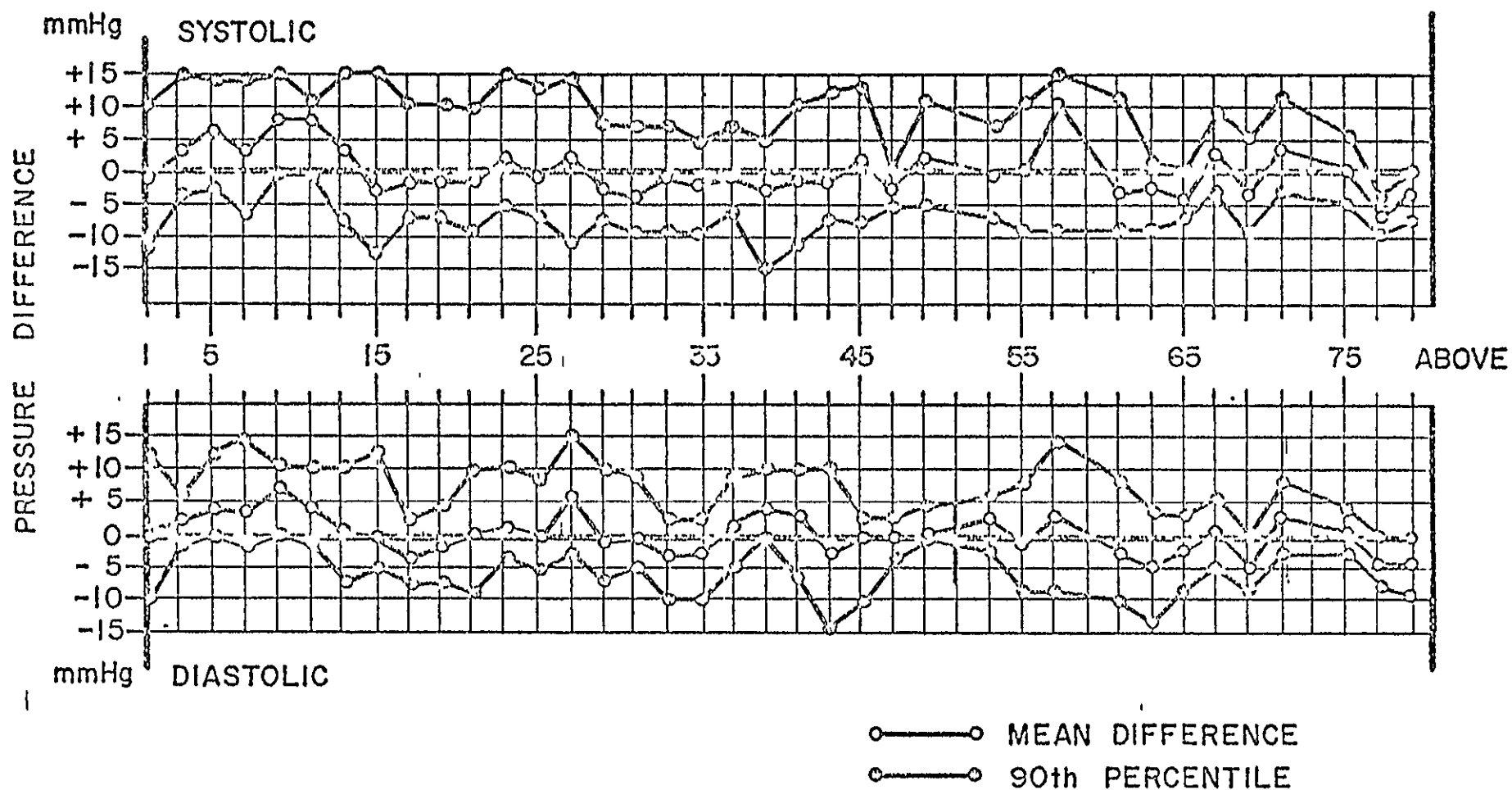
Deviation of ABPS from Korotkoff Blood Pressure Determinations at Various Ages -

The mean difference and 90th percentiles of differences of determinations between ABPS and Korotkoff are plotted vs. the ages of the patients. Positive differences indicate high readings by the ABPS; negative differences indicate low readings.

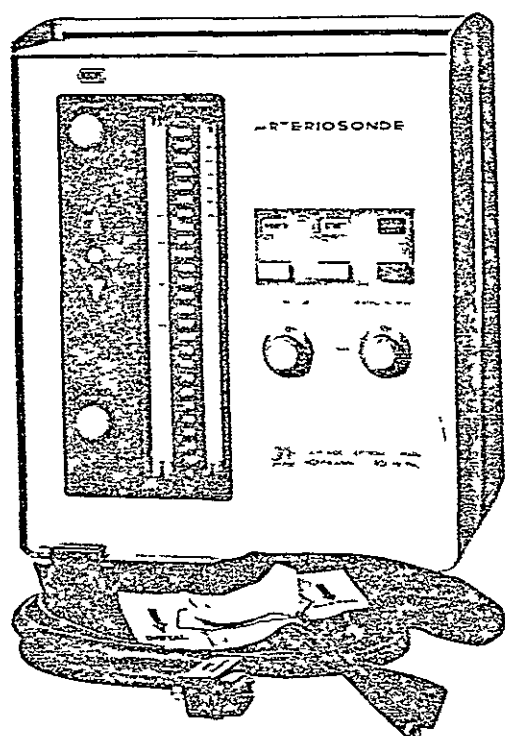


PRESSURE DIFFERENCE BETWEEN ABPS AND KOROTKOFF

Fig. 2



DEVIATION-ARTERIOSONDE & KOROTKOFF vs. AGE



Arteriosonde®

Ultrasonic Indirect Blood Pressure Monitor

for improved patient care in:

INTENSIVE CARE UNITS

CARDIAC CARE UNITS

OPERATING ROOM

RECOVERY ROOM

OBSTETRICS

EMERGENCY ROOM

BENEFITS

The first indirect technique to measure and monitor blood pressure accurately in shock, induced hypotension and noisy environments

Accurate through the entire range of blood pressure, even in the absence of Korotkoff sounds.

Provides an easy means for long-term monitoring.

Reduces the need for direct catheterization

Easy-to-read displays

Patient alarms

Motion artifact recognition

Safe operation

FEATURES

Objective measurement of blood pressure using a Doppler ultrasound technique

Measurement is made by the detection of arterial wall motion and is independent of operator recognition of end points.

Automatically measures at intervals of 1, 2, 5, 10, 15 or 30 minutes. Blood pressure measurement can be manually initiated at any time

Non-invasive measurement. Accuracy is comparable to direct catheterization

Systolic and diastolic pressures are displayed on two illuminated mercury manometers. Readings are held on the manometers between measurements

Adjustable high and low systolic alarm circuit with integral alarm lights. Contacts are provided for remote audible or visual alarm

Motion artifacts are easily distinguishable. Individual artifacts are rejected by the instrument.

Redundant safety features. Underwriters Laboratories listed



SPECIFICATION DATA

Cuff Inflation Pressure:	Adjustable between 70 and 250 mmHg (nominal)	Operating Ambient Pressure:	Sea level to 7000 feet
Cuff Inflation Rate:	Will reach maximum inflation pressure in 5 seconds (-5, -2 sec.)	Humidity:	95% RH maximum
Cuff Bleed Rate	2.5 ± 0.5 mmHg/sec. (meets American Heart Association standard)	Power Requirements:	120 volts, 60 Hz, 1.5 amps
Mode Operation Switch.	Blood pressure reading intervals can be selected manually or made automatically at 1, 2, 5, 10, 15 or 30 minute intervals	Input Voltage Range	95 to 135 volts, 60 Hz
Other Displays and Controls	Power switch and indicator light Start switch and indicator light. Systolic pressure alarm adjustments — high and low. High and low systolic alarm lights Systolic alarm reset switch and indicator light. Maximum cuff inflation pressure adjustment. Artery motion indicator light.	—Power Cable—	Three-prong, three-wire line cord 8 feet long
External Alarm Contacts:	A terminal strip at rear panel is provided for external alarm connection. The load must not exceed 5 amps. inductive.	Mounting:	Self supporting on four rubber legs or permanent support to a cart or horizontal surface
Recorder Connections:	Ten-pin female connector (HLR No. 2302228-101) at rear panel 0 to 1.3v DC (equiv. to 260 to 0 mmHg systolic and diastolic pressures). 1% linearity between 50 and 250 mmHg. Source impedance is 1000 ohms ± 10%.	Shipping, Storage and Handling	Temperature -35°C to +75°C (-31°F to +167°F) Pressure Sea level to 30,000 feet Vibration 1.3g from 5 to 26 Hz Shock. Will withstand 4" tilt drop test (pivoting on any two legs) without damage
Systolic and Diastolic Display:	0-260 mmHg, 2 mm graduations	Equipment Approval:	1. U.L. General Listing for Medical and Dental Equipment 2. F.C.C. Type Approval
Operating Ambient Temperature:	15°C to 40°C (59°F to 104°F)	Fungus Protection:	Materials used in the instrument are non-nutrient to fungus or are sprayed with a non-nutrient material
		Color	Beige and Brown
		Size.	15½" high x 12¼" wide x 12½" deep
		Weight:	40 lbs
		Warranty:	The Arteriosonde and accessories are guaranteed to be free of defects in materials and workmanship for a period of one year from the date of installation

SAFETY DATA

1. Overload protection is provided by a circuit breaker on each side of the AC line.
2. Connection to power distribution system ground is through a three-wire power cable.
3. When used in the presence of flammable anesthetics, the Arteriosonde should be mounted "above the 5 ft. level."
4. The Arteriosonde is designed to limit capacitance-coupled leakage currents to 5 µAmps to the patient through the transducer in the event of accidental loss of external ground connections in the power distribution system or other patient-connected instrumentation.
5. Cuff pressure is automatically released if air pressure exceeds 256 mmHg
6. Cuff pressure is automatically released if AC power fails.
7. Cuff pressure is automatically released within 90 seconds through a redundant circuit if the standard deflation valve fails (on all reading intervals greater than one minute).
8. Maximum ultrasonic energy radiated is less than 50 milliwatts/sq cm (ultrasonic transmitting frequency 2MHz).

EQUIPMENT LIST

The Arteriosonde Model 1213 Blood Pressure Monitor consists of the following:

1. The display and logic unit, housed in a metal cabinet
2. An ultrasonic transducer.
3. An inflatable cuff (standard or anesthesiologist cuff)
4. Gelisonde™ (a specially formulated ultrasonic coupling gel)
5. A 7½ ft. interconnecting cable (an optional 15 ft. cable is also available).

All specifications are subject to change without notice.

For further information, contact your local Roche Representative.

Arteriosonde®
Ultrasonic
Indirect Blood Pressure Monitor

ARTERIOSONDE

PUBLICATIONS, EXHIBITS, PRESENTATIONS

CLINICAL CLAIMS SITES

PUBLICATIONS IN PRESS:

1. Hochberg, H.M., Salomon, H.: Accuracy of an Automated Ultrasound Blood Pressure Monitor. Current Therapeutic Research
In press - (February 1971 issue).
2. Zahed, B., Sadove, M.S., Hatano, S., Wu, H.H.: Comparison of Automated Doppler Ultrasound and Korotkoff Blood Pressure Measurements. Anesthesia & Analgesia
In press - (May - June 1971 issue).
3. Arno, I., Slate, W.: Comparison of Ultrasound and Korotkoff Blood Pressure Measurements in the Obstetrical Service. J. Albert Einstein Medical School.
In press - (February 1971 issue).

SCIENTIFIC EXHIBITS:

1. Ware, R.: A New Method for Indirect Blood Pressure. American Society of Anesthesiologists, 1967 - also at several other meetings.

SCIENTIFIC EXHIBITS (cont'd) —

2. Sadove, M.: Automated Ultrasonic Doppler Blood Pressure Measurement. American Society of Anesthesiologists, Oct. 1970 (showing pediatric transducer results as well as adult results).
3. Poppers, P.J.: Ultrasonic Blood Pressure Monitoring During Induced Hypotension. N.Y. State Society of Anesthesiologists, N.Y.C., December 1970. (First Prize).

PRESENTATIONS ACCEPTED:

1. Sheppard, L.C.: Brachial-Artery Blood Pressure Measured by a New Indirect Method. Assoc. Advancement of Med. Instrumentation, Los Angeles, March, 1970.
2. Tahir, A.H.: The Use of the Ultrasound Technique for Measuring Blood Pressure During Anesthesia and a Comparison With Conventional Methods. Southern Society Anesthesiologists, March 4 - 7, 1971.
3. Godette, A.: The Use of an Automated Ultrasound Blood Pressure Monitor in Early Detection of Pre-Eclampsia. Am. Soc. Ob.-Gyn. San Francisco, Calif., May 3 - 7, 1971.

VI. Clinical Claims Review

A. Literature and exhibits (table III)

B. Pertinent sites

1. Drs. Tahir & Adriani, Charity Hospital, New Orleans - use in anesthesiology.
2. Dr. Poppers, Columbia-Presbyterian, N.Y.C. use in hypotensive anesthesia.
3. Mr. L. Sheppard, U. of Alabama, Birminham, use in post-op cardiac surgery.
4. Dr. A. Gosselin, Miami Heart Institute, Miami, Fla. - accuracy vs. catheterization.
5. Drs. Arno & Slate, Albert Einstein, Phila. use in O.B.
6. Drs. Godette & Clark, Freedman's Hosp., D.C. use in O.B., Rx of eclampsia, O.B. screening.
7. Drs. Zahed & Sadove, Illinois R&E, Chicago use in anesthesia, pediatric transducer
8. Dr. Caceres, Geo. Wash. U., D.C. use in multiphasic health screening

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2. Geddes, L.A.: Ultrasound Kinetoarteriography, The Direct and Indirect Measurement of Blood Pressure, p. 125-128, Yearbook Medical Publishers, 1970.
3. Gray, G.W., Hatke, F.L.: Processing of Doppler Ultrasonic Signals, 21st ACEMB, Shamrock Hilton Hotel, Houston, Texas, November 18-21, 1968.
4. Massie, H.L., Salomon, H., George, M.E.D., : A Correlative Method for Clinical Studies, 21st ACEMB, Shamrock Hilton Hotel, Houston, Texas, November 18-21, 1968.
5. Mount, B.E., Massie, H.L., Auerbach, V., Kishi, J.: Signal Analysis and Processing, 21st ACEMB, Shamrock Hilton, Hotel, Houston, Texas, November 18-21, 1968.
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13. Sheppard, L.C., Johnson, T.S., Kirklin, J.W.: Estimation of Brachial Artery Systolic and Diastolic Pressures by an Indirect Technic, AAMI (in press).
14. Tahir, A., Adriani, J.: Clinical Experience with the Arteriosonde in the Operating Room and Recovery Room, presented at Symposium entitled. Clinical Experience with the Arteriosonde, sponsored by Roche Medical Electronics, February 13, 1970.
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APPENDIX B

CARE AND TRANSPORTATION OF THE CRITICAL TRAUMA PATIENT

1. Flashner, G. A. and D. R. Boyd. "The Critically Injured Patient--A Plan for the Organization of a Statewide System of Trauma Facilities." State of Illinois, Office of the Governor, December, 1970.
2. Moss, G. S. Report on a conference on "Helicopters in Emergency Health Care Services" sponsored by the Washington Information Group, held in Washington, D. C., January 19-20, 1971.



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ALBERT W SNOKE, M D
COORDINATOR OF HEALTH SERVICES

THE CRITICALLY INJURED PATIENT

(A plan for the organization of a statewide system of trauma facilities)
December 1970

Bruce A. Flashner, M.D.
Assistant to the Coordinator
of Health Services
State of Illinois

David R. Boyd, M.D. C.M.
Cook County Hospital

THE CRITICALLY INJURED PATIENT

A plan for the organization of a statewide system of trauma facilities.)

I. INTRODUCTION:

Proposed is a plan to organize a statewide system of facilities for the treatment of the critically injured patient. The focus of our approach is to define an easily identifiable segment of the emergency problem, that of the critically injured patient, and to establish a network of statewide trauma units. The plan will provide adequately staffed facilities, linked together by a communications network, which are equipped for the comprehensive management of seriously injured patients.

The need for a comprehensive program is rapidly becoming evident to the consumer, governmental officials, physicians and many health organizations. At this very moment, in the State of Illinois, as well as throughout the country, someone is being seriously injured. As a result he may face extensive physical disability, prolonged and costly hospitalization or even loss of life. These possibilities occur not because of disinterest in the problem by those concerned, nor even inadequate medical knowledge, lack of money, or equipment, but because the health establishment is unable to provide a successful method for access to proper treatment and care.

At present, there is a dilution of manpower and resources causing a crisis in the accessibility by the public to this type of specialized care. Interestingly, this accessibility is not

of the modern fashionable type which means bringing health care to the disadvantaged, for the poor have immediate recourse to the nearby "County" hospital with its fully staffed and equipped trauma service.

The recently published study on emergency services in the Chicago area documents the problems in the urban community.¹ There are also many studies throughout the country which have proposed solutions to the problems related to emergency service and emergency rooms, including the recent document from the Illinois Hospital Association.² It is believed that as this program proves successful it will act as the catalyst, as well as the foundation upon, which the solution to the total emergency care problem can be structured.

Because this is a proposal for a model, it will not describe at this time the minute details of organization, financial relationships or guidelines of function. Regionalization, financial disbursement of funds, administrative guidelines, involvement of voluntary organizations and possible legislation are some of the many aspects which will be evaluated.

Walter J. McNerney, the president of the Blue Cross Association, in a recent article calls the health administration establishment an underachiever.³ David Kinzer, executive vice president of the Illinois Hospital Association, proposes that immediate steps be taken to create a system of comprehensive emergency service planning.⁴ The time and opportunity has come for this state's

health establishment in conjunction with the state government to solve a serious health problem. Considering the presently available monies, facilities and personnel, the loss of life, disability and lack of accessibility to care can no longer be tolerated.

II. THE TRAUMA PROBLEM:

1. Definition:

Phrases such as emergency care, trauma, acutely injured, emergency services, etc., connote many different things, and because of this a definition of what is meant by the critically injured patient is mandatory. The "critically injured" defines a patient who has sustained a life endangering injury. In addition, certain injuries such as severe eye damage, hand problems, massive facial lacerations, though not specifically life endangering, are critical in that they often result in considerable permanent disability. For this reason we include them in our definition of the critically injured.

This category of injuries accounts for approximately 10% of the emergency service problem. Below are listed certain aspects of this group of injuries:

- (1) These are the most serious problems within the emergency service situation.
- (2) The decision that an injury is critical can in most cases be made without sophisticated professional aid.
- (3) Extensive information gained from the treatment of battle casualties in Vietnam has not been utilized for civilian injuries in the community.

- (4) Criteria that are useful in establishing what is comprehensive emergency room care for ambulatory patients are not applicable to the accident victim with life endangering injuries.
- (5) In hospitals treating large numbers of trauma victims (e.g. Cook County Hospital), it has been shown that there are significant benefits in separating the critically injured from other ambulatory patients. Care can then be rendered in a specialized trauma-care unit.
- (6) From the professional as well as the hospital point of view the problem continues to grow because of complex sociological, geographic and economic factors not related to the technical and scientific advancements which can be utilized for treatment.
- (a) The cost of caring for these patients is enormous. Besides reimbursement not meeting actual costs, one such critically injured patient can tie up equipment and personnel severely needed in other hospital areas.
- (b) The disruption imposed on the hospital facilities is undeniable whenever these cases are not treated in specifically designated locations.
- (c) Adding to the difficulties is the burden placed on the busy practicing physician. Often the patient is injured away from home and is being

cared for by someone other than their personal physician.

(d) When injured away from home there is also increased difficulty in gaining accessibility to medical help.

(e) There are also social problems which cannot be overlooked. The violence in the inner city, coupled with prejudices both racial and economic, can create a problem in accessibility for many urban dwellers.

(7) The consumer is demanding that action be taken to solve the problems associated with bringing modern medical knowledge to all members of the community.

2. Background:

Last year, the National Safety Council reported 11,100,000⁵ injuries from all types of accidents. Wage losses, medical expenses and administrative insurance costs resulting from trauma totaled \$13,600,000,000. The estimated total cost of this pandemic is over \$20 billion annually.⁶

The National Safety Council estimates that 105,000 civilian accidental deaths occur annually, 47,000 of which are due to vehicular injuries.⁷ The one-millionth traffic fatality occurred in 1951; and, if the present rate continues, the two-millionth victim will die by 1976.⁸ Although our traffic injury problem is colossal, it is

estimated that only 15% of the nation's accidents involve autos.⁹ Accidents are currently the third commonest cause of death in the United States, being only slightly less than death from cardiovascular disease and cancer.¹⁰ Under 40 years of age, trauma is our leading cause of death. We are annually experiencing over 15,000,000 significant injuries of children under 14 years of age of which over 16,000 are fatal.¹¹ It is likewise the biggest killer in this age group with the peak incidence being from 2 to 3 years. One-third of all hospital admissions, approximately 2 million per year, are the result of accidents.¹² In one comprehensive study in a large metropolitan area, pediatric cases accounted for 47% of all emergency room visits and traumatic injuries stimulated one fourth of these.¹³

The nationwide problems of emergency medical care delivery are well known. The intensive care and continued close surveillance which are necessary to maintain a critically ill patient are beyond the scope of the average practicing surgeon or physician. The average practitioner cannot devote the necessary time and involvement that is required for the long-term intensive management of these patients. Only where around-the-clock observation is available by hospital based physicians, i.e. senior surgical and medical residents in training, can a high quality of medical care be continually available. Facilities with these personnel available are eager to receive and manage these difficult problems that are truly beyond the scope of one physician. At the present time, there

are many competent medical personnel in the community that perform in an exemplary manner, especially in the acute resuscitation phase. These physicians, unfortunately, have no back up, and then are held responsible for complex problems that are beyond the ability of any one doctor. These patients must be evacuated after adequate resuscitation, which sometimes may even include major surgery, to better equipped and staffed facilities.

The solution of this complex problem will require the cooperation of many interest groups and resources. Of utmost importance in undertaking the project is continuous monitoring of the magnitude of the problem and the results which are obtained. With the use of special computer techniques, coupled with the only trauma registry in the United States, a comprehensive ongoing analysis of this major community health program will be possible.

3. The Trauma Unit Concept:

As a solution to this problem we are suggesting the development of an organized statewide system of specialized trauma units. The trauma unit concept has been described for the city of Chicago. Robert J. Freeark, M.D. and the Chicago Committee on Trauma of the American College of Surgeons (A Proposal for Areawide Planning for Accident Victims, April 1, 1968) have called for the following:

"The plan calls for dividing the Metropolitan Chicago area into 6-8 geographic districts of similar size. A major teaching hospital in each district would be designated as the District Trauma Unit. This

unit would serve as the primary hospital for those accident cases which require transportation by police, fire department or private ambulance. These hospitals, as well as all the other hospitals in the district would also continue to serve both the ambulatory injured and other emergency medical problems as in the past.

The coordination of these District Trauma Units would be achieved by the construction of a centrally located comprehensive facility, hereafter referred to as the Metropolitan Trauma Center. This Center should be part of an existing hospital complex that would provide additional facilities, personnel, consultation and ancillary hospital services to the Center. This Center would be a semiautonomous trauma oriented "hospital" designed, equipped and staffed with the needs of the accident victim in mind. An extensive radio communications network would link the Center with each of the District Trauma Units and with the police, fire department and private ambulance services. The Trauma Center would receive prompt notification of an accident, could dispatch special ambulances or equipment, provide radio consultation to those at the accident scene and advise the various District Trauma Units of the patient's imminent arrival.

The Center would in addition provide special care facilities to the entire Metropolitan Chicago area for the treatment of certain complex injuries, such as major burns, and for the intensive care of patients whose injuries were beyond the facilities and staff at District Units or other hospitals throughout the city.

The Center would also serve as the home base for a helicopter ambulance service, capable of landing at each of the District's Trauma Units or at the scene of an accident or major disaster should this be necessary. These helicopters could supply special equipment or personnel to the scene in addition to providing rapid transportation of patients to the intensive care facilities at the Center."

The trauma unit concept has proven itself to be an excellent plan for the in-hospital care of the critically injured. The plan of early physical segregation of these patients into a specialized area,

staffed and equipped to completely resuscitate and evaluate the serious multiple injuries patient, can be adapted to hospitals of varying size and potential. The accumulative motivation, education and proficiency gained from many centers has been shown to be of great survival advantage in the early management of the critically injured.

A satisfactory outcome after severe traumatic injury is dependent of two basic factors - the availability of initial medical care, and the adequacy of these early therapeutic measures. A study by Frey, et. al. in 150 accidental deaths showed that 18% could have been salvaged with better emergency service.¹⁴ Delays in proper resuscitation and evaluation in life-endangering injuries are the crucial indices to survival. Injudicious or inadequate emergency management can cause unnecessary fatalities and permanent disabilities. The continually increasing incidence and magnitude of serious injuries resulting from high speed transportation, complex industrial equipment, continued civil disturbances, and unpredictable mass catastrophes, necessitates a re-evaluation and re-education of the priorities and techniques of trauma patient care. Changing patterns of traumatic injuries of all types and newer developments in the surgical subspecialties and biomedical disciplines have been responsible for major progress in the field of trauma management.

The first objective of the physician examining an injured person is the preservation of life. When dealing with acute trauma, it is impossible to separate diagnostic and therapeutic measures.

The techniques of the resuscitation are not dependent on an etiologic diagnosis. Airway obstruction, shock and cardio-respiratory failure are similarly treated without knowing the precipitating causes of these disorders.

Once the patient is stabilized he may then be safely evaluated, treated or transported to a more competent facility.

4. An Example of a Functioning Trauma Unit:

The Trauma Unit of the Cook County Hospital in Chicago has experience with over 28,000 seriously injured patients since its beginning in 1966. The Trauma Unit is a specialized facility staffed and equipped to cope with all possible life-threatening emergencies. It is a centralized area where all of the essential hospital resources are concentrated for the comprehensive resuscitation, evaluation and operative needs of these patients. Principles that are used in this specialized facility can be effectively utilized in any emergency room environment. We believe that the trauma patient, because of the probable complexity and severity of his injuries, should be separated from other patients in any emergency room by streamlining his passage through the admitting and the X-ray departments into a special intensive care area. Close surveillance for the telltale signs of shock, aspiration, respiratory distress, and cardiopulmonary arrest can avoid possible catastrophe. Should such untoward effects develop, adequately trained physicians, nurses and paramedical personnel are readily available to institute effective therapy.

5. The Trauma Registry: (National Institutes of Health -
Project Grant #GMS 18003-01)

The complexities involved in the various aspects of severe injuries in conjunction with the deficiencies in our health care delivery system have thus far precluded comprehensive quantitative analysis. With the introduction of modern computer technology, it is now possible thoroughly to investigate the epidemiological and clinical aspects of this major health problem.

A Computerized trauma registry has been developed at the trauma unit of the Cook County Hospital and Research Resources Laboratory of the University of Illinois. It uses an IBM 360/44 Computer and a generalized information retrieval system. The Registry employs a card-oriented data collection procedure, but will soon be utilizing direct entry from remote dataphone terminals. This means that any participating facility can address information into the computer. The international classification of disease categories (adapted 1969) are integrated in the registry, but a new tabulation system is being utilized as the prime patient indexing method.

For the first time, a multifactorial approach to this complex major community health problem is possible. The registry will be instrumental in analyzing mortality rates for graded injuries in paired patients comparative studies, and determining risk factors for various accidental events. The computer cost for such services are far below typical record library expenses.

As information is collected on epidemiological factors, extent of anatomic damage, operative treatment employed, and specific complications, the program will not only be formulating solutions but initiating feedback based on fact rather than intuition.

6. Why has the Problem of the Critically Injured Patient Been Overlooked?

National symposia as well as numerous local workshops have been concerned with this problem. Personal experience and anecdotal analysis do not, however, provide the basis for sound operational approach to this dilemma. The president's address at the American Association for the Surgery of Trauma and the Schudder oration on trauma at the American College of Surgeon's Clinical Congress¹⁵ were directed to these problem areas. Both speakers, at some length, discussed the many self-appointed and multi-directed groups that are presently involved with some small aspect of emergency medical care. There is at present no central or organizational agency involved with the analysis, planning and development of a local or statewide program.

7. Conclusions:

We believe that a statewide organization of trauma units as an approach to the critically injured may provide a working solution upon which to solve many of the deficiencies in emergency medical care in this state. We also believe the trauma unit concept,

if instituted in a statewide comprehensive program, can not only give to Illinois a working life-saving system, but also a model for the nation to utilize.

III. A MODEL FOR EMERGENCY CARE OF THE CRITICALLY INJURED PATIENT:

1. An overview:

The basic concept of this plan is to coordinate the existing hospital facilities in conjunction with the available manpower and add essential equipment as necessary. At present, in Illinois there is no organized plan either on the part of the hospitals or the medical profession for the treatment of critically injured persons, individually or as part of a civilian disaster. Compounding the situation is a public totally unaware of the facilities available and of the medical potential in the community.

The proposed model has three functioning levels to solve these problems. The basic unit is the emergency room of a community hospital and, if present, its intensive care unit. It functions as the immediate provider of care. Attached to its emergency room is a specialized ambulance of the type recommended by the American College of Surgeons. ¹⁶ According to Illinois Law 568, this unit is a Type B emergency room, one that is fully equipped, providing 24 hour service and has a physician on duty at all times.

Servicing many local basic units is the areawide trauma center. This is a hospital with a house staff, teaching programs, specialized treatment units, and many specialty services not available at the local level.

Finally, there will be a small number of university-based regional trauma centers where the full advantages of modern science can be utilized for the care of patients whose condition warrants intensive diagnosis and therapy. One of the centers will act as the coordinator and administrator of the proposed state program.

2. The Local Hospital Unit

This is a hospital which fulfills the following criteria. Although many criteria are consistent with State Law 568, this program requires more stringent organization and trained personnel.

(1) There is 24 hour medical and paramedical coverage which can provide comprehensive emergency care to a critically injured patient. Personnel are available to make diagnoses and institute basic resuscitation and treatment necessary to sustain life and to make the decision to continue therapy within its own confines or referral by helicopter to the areawide center will be made.

(2) It must have competent emergency facilities which will not require large sums of money for the addition of essential equipment.

(3) A desire on the part of the hospital and professional staff to offer emergency care to an area which includes an ambulance round trip of no more than two hours (i.e., approximately a 50 mile radius). In urban areas, this would by necessity be a much smaller distance and, in many cases, might be no more than one or two miles.

(4) There must be a specific location within the hospital which can be set aside and designated for the care of trauma victims. On hand would be the necessary equipment, medication and, most important, the personnel.

(5) The type of personnel will vary with the specific hospital. The following is a minimum suggested staff:

(a) A staff physician to act as the local trauma coordinator. In small communities, this physician may be the only doctor with trauma training while in others he may be the senior staff surgeon. In any case, it is his responsibility to see that the program functions properly. It does not imply that he is the physician in charge of all patients, the only referring doctor, or even responsible for medical care at all times. His duties encompass keeping the facilities functioning, the program vitalized, the paramedical personnel trained, and the program data collected and transmitted to the central computer.

(b) At his disposal is at least one paramedical, trained individual who is available at all times to assist him.

(6) A hospital based ambulance of the type specified by the American College of Surgeons. This ambulance, which is equipped to handle an injured person at the scene of the accident, is manned by individuals with training in the care of the severely injured. The criteria for this training has been detailed by the American College of Surgeons. The key to the program is the education of the personnel involved at all levels of the system.

(7) There are two significant aspects regarding paramedical personnel. First, there must be an immediate upgrading in the level of care afforded at the site of injury by ambulance personnel. Second, the initial care provided by the professional staff at the designated local trauma unit. Central to the theme of this program is the desire to utilize, wherever possible, the present staff properly trained in the care of the severely injured. Where applicable, personnel can be retrained through grants, in order that at least one individual trained in trauma is available to provide 24 hour consultation coverage.

(8) A fully coordinated system of communications between ambulance, hospital and the areawide center.

The most difficult problem is not how to create this local emergency care facility, with its specialized personnel and equipment. The problem will be to pool and coordinate the local community's resources into one. This means reorganization through voluntary action among many local hospitals in some communities and, in others, some arbitrary choice between two duplicating and inefficient emergency rooms, sometimes very closely situated.

3. The Areawide Hospital Center:

This institution must have an accredited teaching program in surgery, though university affiliation is not required. This facility will be the referral center for a number of basic trauma units. As the center for local units, it will provide four vital functions:

(1) Provide service to the local community in which it is situated by functioning as a type "B" unit.

(2) A communication center which will give advice both medical and technical to the local hospital trauma center.

(3) A helicopter service. Any patients, whose injuries or status requires more sophisticated care either because the problem cannot be handled at the local level or the facilities are not available, will be flown to one of a dozen or so designated areawide centers. The service must be available on no more than a four hour basis (300 miles). At present, approximately 40 hospitals in Illinois have heliports which are not utilized.

(4) Special care units for the treatment of trauma victims, which provides sophisticated study, treatment and equipment, complemented by the full range of medical specialties. These would include blood banks, training centers, special laboratories, hemodialysis facilities, etc.

(5) Meet all the criteria for a comprehensive unit as "type A" set forth in State Law 568.

4. The Regional Center

Because these centers will function as the regional planning and coordinating hubs, be responsible for financial disbursement, train and educate professional and non-professional workers at all levels, have super specialty facilities (burn units, transplant facilities, hyperbaric chambers, etc.), they must, by dint of available

manpower and facilities, be located in the university medical centers throughout the state. At present, this means six in Chicago and the proposed centers at Springfield, Carbondale, Rockford, and Peoria.

These centers at the same time they serve many areawide centers, would also provide basic facilities to their local neighborhoods.

Since the manpower and facilities for care are now available at this level, the only difficulties are those of organization and administration. These centers, with their training programs and facilities, will in most cases be delighted to assume the job.

The regional center will be tied by radio and dataphone communications to its many member areawide institutions. The helicopter service based at the areawide hospitals would serve as its transportation arm.

There is no intention to have routine cases forwarded to the regional center. The vast majority of cases would be handled at the areawide level - Type A. In some areas most of the routine work can be accomplished at the local level - Type B.

5. The Problem in the Cook County Area

This model is not applicable to the Cook County area without specific modifications. There are a number of specifics to the Chicago-wide area which must be considered. Many of these problems are detailed in the emergency service report from the University of Chicago.

(1) A police policy which requires that patients be brought to the nearest hospital emergency room.

(2) A large indigent population, without easy access to medical care, geographically isolated, where trauma is mostly secondary to human violence rather than accidents.

(3) Six medical schools, of which five have their own medical centers.

(4) Non-university affiliated medical centers.

(5) A long history showing an inability to solve problems by cooperative organization because of petty jealousies, both administrative and medical in content.

(6) There are many others which are unique to any large urban community and need not be detailed here.

On the other hand, many of these so-called difficulties, if properly coordinated, can be turned into advantages. In the Chicago area, an abundance of facilities and trained manpower is presently available. Very little in the way of seed money, new personnel or funding is necessary, but rather a willingness to accept a plan of action by the member hospitals and medical staffs.

The problem created by the requirement that injured persons be taken to the nearest emergency room, which in the past has been a major obstacle to comprehensive planning, has been relieved by recent State Bill No. 568. This law allows a group of hospitals to designate levels of emergency room care. Thus, the police can take seriously traumatized patients to the nearest designated emergency room.

In Cook County, most participating hospitals will function as areawide Type A comprehensive emergency treatment centers. Since many of them have well equipped emergency rooms and trained personnel, they will handle most non-critical injuries. The small Type B and C standby and basic hospital emergency rooms can be designated as emergency rooms for ambulatory trauma patients. The critically injured patients will be sent directly to the regional hospitals.

The areawide, Type B, hospitals will be divided into regions, each relating to one of the six medical centers. The medical centers, as in the rest of the state, will be responsible for data collection, financial responsibility, and training as described in previous sections. However, in the urban program, they will be charged with the care of all critically injured persons and, whenever possible, these patients will be brought directly to their trauma centers.

It is anticipated that certain hospitals will not desire entry into this plan. It must be emphasized that the program is voluntary, and it is hoped that as the plan proves successful, institutions at all levels will seek admission.

6. The Administrative Center

The medical center at the University of Illinois will operate as the administrative center for the program. The reasons are as follows:

(1) This program will be organized and funded through the state government and thus should reside in a unit of the state.

(2) With the expansion of the University of Illinois Medical School throughout the state, administrative control can follow normal and existing lines of communication. -

(3) The Medical Center Campus at the University of Illinois does not at present have a structured trauma unit. By virtue of its accessibility to Cook County Hospital, it will utilize that facility for trauma training. The Cook County Hospital unit will serve in lieu of creating another unit at the University Hospital.

(4) The University has the only statewide educational system which will be utilized for the training of personnel.

(5) It will act independent of vested economic interests.

(6) The University's new School of Public Health will offer necessary academic stimulation and planning personnel.

IV. AD HOC COMMITTEE

To facilitate and organize this program a committee under the auspices of the State Comprehensive Health Planning Agency shall be organized. Membership will be:

- (1) Senior Consultant in Surgery, University of Illinois
- (2) Educator-University of Illinois-Dean of School of Public Health
- (3) Two lawyers (a) Chicago (b) Southern Illinois
- (4) Consumers (three)
- (5) Students - Medical (two)

- (6) Illinois Hospital Association
- (7) Illinois Medical Association
- (8) Medical Economist
- (9) Governor's Office
- (10) Mayor of Chicago Office, Department of Public Health
- (11) State Department of Public Health
- (12) Bureau of the Budget, State of Illinois
- (13) Illinois Regional Medical Program

In addition, members of the State Comprehensive Health Planning Agency will serve as staff.

V. INITIATING THE PROGRAM

It is the intention of the State Comprehensive Health Planning Agency to begin the establishment of the plan for this program. Wherever Regional Planning agencies exist, they will be fully utilized.

In the next six months the following objectives will be undertaken:

(1) Classification of the state's hospitals, using the criteria previously outlined, into the three prescribed levels for the treatment of the critically injured.

(2) Plan the geographic distribution of the three levels of hospitals.

(3) Explanation of the program to all parties concerned.

(4) A search for federal funds for the program. It is anticipated that this will come from many sources and at different

times. However, the program should begin as soon as seed money is delivered.

(5) Devise the plans for ongoing education of all personnel.

(6) Set up the monitoring system for collection of data, location of research spinoff, and methods of initiating feedback of new concepts into the program.

(7) Expand the trauma registry to include the whole state.

(8) Detail specific legislation as required to implement portions of this program.

VI. THE EMERGENCY SERVICE PROBLEM:

The reasons for attacking the problem of the critically injured rather than the whole emergency service situation has been described. However, it should be obvious that the two will be very difficult to separate. It is expected that the committee will, by necessity, also evaluate the emergency service problem throughout the state and formulate programs to provide solutions.

VII. METHOD OF FINANCE:

An immediate search for funds is to be undertaken by the ad hoc committee on the critically injured patient of the state Comprehensive Health Planning Agency. These funds will be accumulated over a period of time and the program is to be implemented as plans are accepted and as funds are made available.

Only when the program is satisfactorily organized will it be separated from the state Comprehensive Health Planning Agency.

Below is a proposed list of areas in which to search for funding:

(1) Federal government

(a) Federal Highway Program

(b) Department of Health, Education and Welfare

(c) Department of Defense and Civilian Defense Program

(d) Federal Manpower funding

(e) Hill-Burton Program (now authorized to spend \$30,000,000 for grants to help hospitals for the up-dating of emergency rooms).

(2) State of Illinois

(a) General funds

(b) Highway funds

(c) Legislative appropriation

(3) Illinois Hospital Association --

(4) City of Chicago and Cook County

VIII. SELLING THE PROGRAM:

At the present time, there are numerous agencies studying the emergency medical care problem. Each of these agencies and commissions are groups attempting to define some chosen aspect of the problem. At the completion of these necessarily limited studies there has been no central or authoritative forum where their findings can be presented.

A very real problem is the implementation of such a broad-based program. The development of any major reorganization scheme and the concomitant distribution of medical resources, will, unfortunately, meet with resistance to change. However, by working with the medical societies, the hospitals, and most importantly, the physician in the field, an honest aggressive sales pitch should return the necessary cooperation and support. Support will be obtained by showing these groups that the basis of our plan is to involve the physician and his local hospital and staff with the responsibility for the primary treatment and transfer decisions. To carry out these tasks they will be given the necessary essential modern equipment. An ongoing education extension program is envisioned to continually update professional and paramedical personnel.

The entire emergency health care delivery program will be possible only through the auspices of the local county medical societies, and specialty organizations, such as the Committee on Trauma of the American College of Surgeons.

IX. ILLUSTRATIONS:

A. The Present System

A youthful 31 year-old mother of two, driving along an Illinois highway, is involved in an automobile accident. Her car, skidding on a patch of ice, careens off the road and hits a telephone pole. She is knocked unconscious with head injuries,

and associated abdominal and extremity damage. It is one hour before the State Police find her wrecked auto. The nearest town is 25 miles away and the police request an ambulance. Because of the late hour and lack of any plan or organization to treat accident victims, it takes another 90 minutes before the victim finally reaches a small community hospital with a standby emergency room. There is a nurse on duty but she has no formal trauma training and another two hours elapse before a physician arrives to render care.

The victim, though requiring intravenous fluids, chest tubes, care of a fractured leg, and other immediate therapy; receives only basic first aid treatment. Through no fault of the medical personnel in attendance, the proper equipment is not available, nor, if available, can it be mobilized.

It takes another five hours before the proper personnel can be mobilized to perform surgery. The patient's condition is followed during the next few days by a limited staff already overworked with other medical problems and duties.

Again, the patient's condition deteriorates. This time because the magnitude of her injuries has caused slowly progressive head and kidney damage. There is another delay of three days before these complications are noticed because of the shortage of personnel and lack of specialized detection equipment.

As often happens, the attending physician decides that this patient should be referred to an institution capable of dealing with a problem of this magnitude. It may very well be that he is fully

trained in the care of trauma but without support, there is very little that can be accomplished. — — —

It takes another 48 hours before arrangements can be made to transfer this patient to another hospital some 175 miles away. The trip takes four hours by ambulance during which time the patient's condition steadily declines. Finally reaching a 250 bed hospital which has a multitude of specialists, and the necessary equipment, little can be offered because of the delay, and the patient expires three days later.

All of the individuals involved, from the state highway patrolman, to the neurosurgeon performing the last ditch, life-saving operation, are filled with remorse. They feel that everyone did all that was possible. In fact, it may be another year before another accident of that type occurs in the community and by that time the tragedy will have all but been forgotten.

However, if one accumulates these individual accidents on a statewide basis, the overall loss of life, prolongation of hospital stay, and extensiveness of individual disability becomes frightening in scope and magnitude.

B. The Future Program

What occurred in the previous example should not have happened. The State Police would call the nearest hospital with a "Type B" trauma emergency room. In our previous example, instead of the patient going to the unprepared hospital, she might have

gone in the opposite direction to a hospital of 250 beds with a fully staffed trauma facility. The unit is notified before the patient arrives and a pre-planned program is instituted. Minutes after the patient is examined in the emergency room it becomes apparent that the problem is complex and will require many specialists having available a full range of paramedical services.

The areawide center is notified about an impending transfer. At the same time, advice is offered regarding the latest treatment for severe head injuries.

The local physician requests that helicopter service be initiated. With the help of the paramedical team the patient is stabilized and therapy instituted. It takes three hours before the accident victim arrives at the regional center. The most sophisticated treatment available is utilized in treating the victim, and during the next few days she remains under 24 hour care because of the presence of a house staff. She undergoes two major surgical procedures. During her recovery period, which spans a period of four weeks, the professional staff works with the knowledge that a university center with specialized services is ready to back them should the need arise.

X. CONCLUSION

Contrasting the two brief examples above, it is obvious that there is no new facility or expensive cost requirement. All that must be accomplished is organization of a system that presently exists in a fragmented form.

Consider the following:

- (1) The patient's insurance covers many of the medical costs.
- (2) Whenever hospital stay is diminished, a substantial insurance savings results.
- (3) Choice of referral still remains with the responsible physician.
- (4) Whatever initial costs are incurred in organizing the program will be quickly offset by the economic savings accumulated by decreasing losses in life, loss of work time, diminution in permanent injury and the fuller utilization of existing facilities.
- (5) The accumulation of scientific data, coupled with improved training and education of personnel at all levels.
- (6) The first statewide system in the United States which can bring to its citizens the full impact of medical care that has been learned from the treatment of battle casualties from Viet Nam.
- (7) A statewide system to be used as the framework for a civil defense plan in time of disaster.

The tangible return of comprehensive and integrated emergency care system will have to be evaluated. Monitoring of time and morbidity factors will be made possible by the use of the Trauma Registry and can document the advantages. The ability to organize volunteer help and community financial support for ambulance service and emergency care costs may be an indication of the productiveness of this plan. The citizen's awareness that he will have an equal opportunity to receive optimal emergency medical care when it is most needed will result in considerable community enthusiasm and support.

These programs will entice previously trained personnel, as well as future aspirants into the health care system. Specific aim will be made at the medical corpsman who have been extremely well trained by the federal government to remain in the health care delivery system. The program, as it is developed, will enhance the performance of professional and para-professionals at all levels.

At the present time there is a great deal of duplication in medical research. In any major institution, one or more investigators may be involved with very similar and related research interests. The awarding of grants in many instances is not well-planned. While competition is good, duplications of expenditures for personnel and equipment can no longer be tolerated. A Central agency could best allocate or advise in the distribution of monies in the best interest of the public needs. Also, with new computer methodology, a combined interdisciplinary study coupled with institutional multiple approach can be developed for the benefit of all.

As the problem of the critically injured patient is solved, new ways will be developed to evaluate and manage other urgent medical problems. The basic geographic regionalization, if utilized successfully, can have wide application in the solution of many health care problems.

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February 8, 1971

Mr. Lonnie Von Rinner
National Academy of Engineering
2101 Constitution Avenue, N.W.
Washington, D C. 20418

Dear Lonnie:

Enclosed is a copy of the formal presentation given at the helicopter information meetings in Washington plus my synopsis of the high points.

Best Wishes,



Gerald S. Moss, M.D.
Attending Surgeon
Division of Surgery

GSM:bjl
Encl.

INTRODUCTION

This meeting was sponsored by the Washington Information Group and was entitled Helicopters in Emergency Health Care Services. The participants included military helicopter specialists, civilian ambulance services, hospital administrators, helicopter manufacturers, physicians interested in trauma, representatives from various governmental agencies including the Department of Transportation, Health Education and Welfare, and highway systems consultants. The objective of the meeting was to review the national experience to date in incorporating the helicopter into the health delivery system, especially regarding its use in the acute management of trauma.

I have included a schedule of the formal presentations. In the following, I have attempted to synthesize the important and practical points emphasized at the meeting.

BASIC CONCEPTS

Before reviewing the current programs it would be helpful to explore the various kinds of possible helicopter systems.

First is the idea of single versus multiple use. In the single use system, the helicopter is used solely as an ambulance and has no further function. This has the advantage of clear lines of responsibility and rapid response time. However, it is an inefficient system because studies have shown it will be in use only a small fraction of the time. In a multiple use system, the helicopter is operated by the state police and is used for crime

detections, traffic survey, riot control and other community functions.

This has the advantage of being a more efficient system from the point of view of cost effectiveness and is the most popular current approach.

Another idea relates to civilian versus military helicopters.

--The civilian agency is usually the state police. The advantage of the civilian approach is that complete control of the helicopter system remains in the hands of the trauma system. Decisions regarding personnel, flying time, qualifications, response to a particular accident, and numerous other details are decided by the people in the trauma system rather than the military. A major potential disadvantage is cost. The usual 2 litter helicopter costs approximately \$300,000. Maintenance costs per year are \$100,000. The military system has several advantages. The helicopter and crew have been tested in Vietnam and the system has been well worked out. From all the data as well as my own personal experience, the military performs this function in an almost flawless fashion. The problem with using the military is fundamentally one of mission responsibility. In the long run, it is unlikely that military helicopters will be authorized on a permanent basis, to support a civilian evacuation system.

Communications is another important issue. The ideal system would include two way verbal communicators between chopper, accident area, central dispatcher and receiving trauma unit. The key point to emphasize is that once evacuation has been effected, direct verbal communication is essential. The role of the dispatcher is to direct the helicopter

to the accident site and then to direct the helicopter to the appropriate trauma center. Such communication systems currently exist. They usually involve the fire department, police agencies, and participating hospitals.

Various kinds of helicopters have been tested. It is generally agreed that the vehicle should have space for 2 litters, room for an attendant to stand, and provisions for IV infusions, O₂ therapy, provisions for control of external hemorrhage and maintenance of the airway. In addition, equipment for extraction from the automobile should be included. Helicopters made by Bell, Boeing, Fairchild Hiller, and Sikorsky were the ones most prominently mentioned. These all have a speed of approximately 150 mph and a range of 300 miles.

In the civilian system, it has been suggested that 3 people be aboard, a pilot, a corpsman, and a police observer. All three are generally Vietnam veterans who have graduated from the police academy. The corpsmen receive additional training from one of the trauma centers. When the mission is crime detection, all three function as policemen, when the mission is evacuation, the police observer remains at the scene and is picked up by a ground vehicle. There is no enthusiasm for taking surgeons to the scene of the accident. Most agree that the key issue is rapid movement of the patient to a fully equipped hospital. Nor is there any enthusiasm for building elaborately equipped "flying operating rooms". They are impractical and the cost would be fantastically excessive.

CURRENT SYSTEMS

A number of demonstration systems were reviewed, these were federally sponsored projects. Three of the important ones were HASTE, AMES and MAST. HASTE (Helicopter Ambulance Service to Emergencies) was funded by the Department of Transportation to a commercial helicopter company in St. Paul, Minn. AMES (Air Medical Evacuation System) was carried out by the Arizona Highway Patrol and was a multipurpose system. MAST (Military Assistance to Safety and Traffic) has been carried out in the San Antonio, Texas area. Military units from the 507th Air Ambulance Company, from Fort Sam Houston participates. This involves 15 helicopters and 21 pilots.

These and several other systems are all small, federally funded, short range programs. As far as I can tell, there is only one system that appears to be viable, growing and supported in large part from local funds. This is the program associated with the trauma center at the University of Maryland. The director of the unit is Dr. A. Cowley. The system owns two helicopters, run by the state police. It is used for traffic surveillance, crime detection, riot control as well as trauma evacuation. The crew consists of 3 state troopers-one pilot, one police observer, and the corpsman. Flying time from anywhere surrounding the Baltimore Beltway to the trauma unit is only 5 minutes. Air way control and IV infusions are started on the ground. If the accident is not

life threatening, then ground transportation is used. If in the judgement of the trooper - corpsman, it is life threatening, then the air ambulance is used.

The helicopter has also been used in the city itself for emergency evacuation to the trauma unit. This has involved landing in the street between the buildings, in a vacant lot, or if the patient is inaccessible, he is transported part way by ambulance, and the remainder by helicopter.

The communications in the Maryland program was the state police network. This works satisfactorily, but there is no direct verbal communications between helicopter and trauma unit.

FUNDING

Several federal agencies were represented including the Department of Transportation, H.E.W., R.M.P., and several congressional aides. Their theme was quite clear. There is little federal money available to purchase or maintain helicopters.

Support from Hill Burton or R.M.P. money is unlikely. There may be some support available from the Law Enforcement Assistance Act Program (L.E.A.A.). Those programs with the best chance federal support would have the following:

1. a large measure of local support (state funding),
2. a regionally organized program,

3. an effective program of designating which hospitals in the region have emergency rooms capable of dealing with multiple organ trauma,
4. multipurpose use of the helicopter,
5. consultation with local R. M. P. and comprehension health planning agencies.

EMERGENCY MEDICAL COMMUNICATIONS

A report of the
Subcommittee on Emergency Medical Communications
and prepared with the aid of the
Committee on the Interplay of Engineering with Biology and Medicine
National Academy of Engineering

Committee on Emergency Medical Services
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NOTICE

The study reported herein was undertaken under the aegis of the National Research Council with the express approval of the Governing Board of the NRC. Such approval indicated that the Board considered that the problem is of national significance, that elucidation or solution of the problem required scientific or technical competence, and that the resources of the NRC were particularly suitable to the conduct of the project. The institutional responsibilities of the NRC were then discharged in the following manner:

The members of the study committee were selected for their individual scholarly competence and judgment with due consideration for the balance and breadth of disciplines. Responsibility for all aspects of this report rests with the study committee, to whom we express our sincere appreciation.

Although the reports of our study committees are not submitted for approval to the Academy membership nor to the Council, each report is reviewed by a second group of appropriately qualified persons according to procedures established and monitored by the Academy's Report Review Committee. Such reviews are intended to determine, *inter alia*, whether the major questions and relevant points of view have been addressed and whether the reported findings, conclusions, and recommendations arose from the available data and information. Distribution of the report is approved, by the President, only after satisfactory completion of this review process.

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FOREWORD

Starting with its report, "Accidental Death and Disability: The Neglected Disease of Modern Society," published in 1966,¹ committees of the Division of Medical Sciences, NAS-NRC, have focused on the many problems which plague the provision of emergency medical care in this country. Subsequent reports specified guidelines for the training of ambulance personnel and others responsible for emergency care,^{2,3} medical requirements for ambulance design and equipment,⁴ and design and performance requirements for ambulance vehicles.⁵ A recently-released report documents the roles and resources of federal agencies that have responsibilities to support comprehensive emergency medical services.⁶

Throughout these and other studies, the key role of communications in linking the multiple elements involved in emergency medical services (EMS) systems is emphasized. Much has been said about the need for an integrated, coordinated communications network that brings together all of the components of the emergency medical system in an integrated and coordinated manner to provide optimum care using well-established but often poorly implemented principles of modern emergency medicine.

It is commonly assumed, by those concerned with emergency medical care, that the communications problem is either to buy equipment that will serve existing facilities or to buy the communications equipment first and then design an emergency medical system around it. This report takes the position that the first job of those desiring emergency medical services is to design the emergency medical system in its entirety, with whatever legal, technical, sociological, political and other expertise may be needed to meet the individual requirements of that community. Only

after it has clearly defined its emergency medical needs and has designed a system to meet those needs should a community look for the communications equipment that will serve to tie together the various elements of the system. This report, therefore, concerns itself first with those elements essential to any emergency medical system, and secondarily, with the kinds of equipment that may be needed.

This study of emergency medical communications was requested by the Office of Emergency Medical Programs, Department of Transportation and by the Division of Emergency Health Services, Public Health Services, to define the functions of communication, establish communications systems requirements, and recommend means of implementing EMS communication networks. In addition, through the National Academy of Engineering, the National Aeronautics and Space Administration supported the drafting of this report as part of its search for appropriate ways in which the technologies of aeronautics and space can be applied to other national needs.

This report is addressed specifically to the communications routinely required by an emergency medical system. Thus, it does not define in detail the communications requirements relevant to a disaster or other mass treatment situation, nor does it attempt to resolve the myriad related problems that beset any emergency medical system, such as use of ambulances for non-emergencies, overcrowding of emergency departments with non-emergency patients, jurisdictional conflicts between emergency services, ways of maximizing the usefulness of noncommunications elements of the emergency medical system, or ways of insuring equality of service to neighborhoods of different socio-economic status.

Some of the material in this report has been said before. However, much appears for the first time, in particular the recommended design criteria for EMS communications systems and the material in the three

Appendices. The Subcommittee endeavored not only to collect in one document a statement of need, function and design for the use of those in the nation who are charged with implementing EMS communications systems, but also to identify the total emergency medical system which must exist before a communication system can be instituted.

I owe a debt of gratitude to all of the Subcommittee members who gave unstintingly of their time to perform this study. In addition, recognition must go to Dr. Sam F. Seeley who, as Professional Associate in the Division of Medical Sciences, devoted a major portion of his time and effort in recent years to drawing national attention to the deplorable state of emergency medical care and who made many invaluable contributions to this study.

Finally, we must acknowledge the efforts of the staff of the Committee on the Interplay of Engineering with Biology and Medicine, National Academy of Engineering: in particular, Charles W. Garrett (Executive Secretary) and Jean M. Ruffin (Research Associate) who contributed necessary technical knowledge and who drafted the manuscript, and Marianna Shepard who diligently and precisely prepared the copy. Joe and Gladys Specht and Jean Stalle also contributed hundreds of hours to preparation of early drafts of this report.

J. Cuthbert Owens, M.D.
Chairman, Subcommittee on
Emergency Medical Communications

October, 1972

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INTRODUCTION

In recent years, accidental death and disability have come to be recognized as a major health problem; accidents are the leading cause of death in the 1- to 38-year age group,⁷ and the fourth leading cause (following heart disease, cancer, and stroke) in the population as a whole. In 1970, 50 million accidental injuries killed 114,000, temporarily disabled over 11 million, and permanently impaired 400,000 American citizens at a total cost of more than \$27 billion.⁸ An even greater number of deaths follow such medical emergencies as heart attacks, respiratory difficulties and stroke. Coronary arterial disease is the leading cause of death in the adult U.S. population,⁹ claiming 500,000 lives per year, over 60% of these from sudden heart attacks. More than half of the latter now die before they reach a hospital,¹⁰ 40 to 75 percent in the first hour after the onset of symptoms.

Many of these lives could be saved and much disability prevented simply by the systematic application of already established principles of emergency medical care.¹¹ A study of 168 highway fatalities in Vermont showed that the injuries of 23 percent of those who died need not necessarily have been fatal. There were similar findings in a University of Michigan review¹² of autopsy protocols of 159 motor vehicle accident victims. It was estimated that with prompt and adequate emergency care at the scene and en route to the hospital, 18 percent could have survived to recover their previous state of health, and another 6 percent could possibly have been salvaged. For instance, in Jacksonville, Florida, the EMS system has in four years reduced the mortality rate of traffic crash victims by 24%. Further, the mortality from heart attacks can be significantly lowered by an efficient, rapidly responding medical team, as shown by demonstration projects, both in this country and abroad.^{13,14,15,16}

An emergency medical services system should provide quality care to any patient in the shortest possible time. This requires the coordinated efforts of doctors, nurses, emergency department staffs, ambulance services, ambulance attendants, police and fire departments, traffic control units, military bases with helicopter; local, regional, state, and federal officials; health departments, disaster units, and others, including the general citizenry. The system must meet the needs of the critically injured as well as the poison case, suicide attempt, drug overdose, heart attack patient, and diabetic in coma; the indigent as well as the non-indigent, and rural as well as city-dwellers. There must be immediate access for patients requiring emergency care, rapid decisions for their management, and flexibility and procedures to cope with the rare and unusual demands of a major catastrophe.³⁶

An EMS system should also include realistic ways of rapidly implementing effective safety programs.

The EMS System Must Precede the Communications Subsystem

It is clear that the EMS system involves such obvious items as hospitals, clinics, doctors offices, and ambulances. It is not generally understood that it also involves a variety of other elements including a transportation subsystem, various physical facilities, a cadre of manpower and an administrative structure which provides the operational framework for the system and coordinated, cost-effective management of its resources. Furthermore, EMS system planners must take into account the training of its dispatchers and staff and of its medical, paramedical, and other personnel; the levels of treatment available; the education of the public in preventive medicine, in recognition of emergencies, and in use of the EMS system; the demographic characteristics of the population served; and the interactions of the EMS

system with other public and private community services (police, fire, non-emergency medical care, etc.). All these components, or subsystems, must be addressed together and simultaneously if the nation is to improve its ability to provide sound emergency care.

Essential Elements in Emergency Medical Services

There are six essential elements in any emergency medical services (EMS) system that affect the quality of care provided. These are:

1. Entry into the system, which depends upon training of the citizenry to recognize and report the need for emergency medical care, upon a communications link permitting rapid access into the system, and upon medical screening of calls to assure that appropriate medical assistance is promptly dispatched.
2. Emergency care at the scene and in transit, which is dependent on response time, the training of emergency medical technicians in ambulances, the design and equipping of ambulances or other vehicles; and access to physician supervision and consultation.
3. Transportation, which is dependent on ambulance availability and dispatching efficiency; availability of other transportation modes such as aircraft and helicopter; the role of non-medical transportation such as private autos, taxis and buses; and the degree of coordination with police, highway department, aeronautical and other relevant agencies. Coordination of communications between geographic areas is of importance when an ambulance must cross jurisdictions having different emergency medical frequencies.
4. Screening, control, and coordination, which depend on the EMS system organization and administration; the degree of integrated planning and operations with other emergency response bodies such as fire, law enforcement, public utility, and civil defense agencies; the degree to which the EMS system incorporates the necessary decision-making processes; the involvement of local

state, and federal legislative and executive branches, community emergency medical councils, and medical societies; and coordination with all of these groups in neighboring areas.

5. Communications, which is dependent for its effectiveness on the adequacy with which the design of the total EMS system, for which communications should be the unifying element, meets local needs; on the nature and effectiveness of radio and special telephone or other message transmittal circuits that are contained within the EMS system; and on the means by which communications systems external to the EMS system -- public telephone systems, road signs, fire, public utility, and business systems such as those used by taxis and buses -- are integrated into or utilized by the total EMS communications network.

6. Emergency Care in Hospitals, which is dependent on the quantity and training of emergency department paramedical and physician staffs; the nature, availability, and identification of emergency department facilities and equipment; the access to specialized care facilities such as intensive care, coronary care, trauma, and burn units, availability of physician specialists and laboratory services; and the access to, and coordination with, other medical in- and out-patient, public health and rehabilitation services.

Communications in the broad sense implies the transmittal of information, and, in equally broad terms, EMS communications includes all of the devices and procedures used to transmit information within and between components of the emergency medical system and with the public it serves. It provides the means for the patient to enter the EMS system, for resources to be sent to him, and for supervised treatment to be provided at the site and in transit.

Thus, highway signs denoting emergency facilities, written records of patient data, published standard operating procedures on all phases of EMS activities, staff training aids, and the communications involved in public education are each a part of the total emergency medical communications package.³⁷

While not ignoring these important considerations, however, this report is most specifically concerned with "telecommunications" in EMS; that is, radio and landline (telephone) links that transmit voice and data together with the necessary operational principles and administrative techniques.

Present Lack of Communications

Most of our nation's communities have no coordinated emergency system, much less a medical communications network. What is usually found is an ineffective patchwork of unrelated emergency systems as identified in two recent state surveys.^{17,35} It was found that the capability for mutual communication among hospitals, ambulance services, law enforcement and other agencies was often poor or sometimes entirely lacking. There was little or no communication across political boundaries even though, for example, there were 4,422¹⁸ ambulance runs in one year crossing those boundaries. Within a given jurisdiction, there were usually a multiplicity of separate or independent systems variously serving law enforcement, fire, civil defense, and emergency medical needs. Of the four, medical services had the most poorly developed communications system.

Even though rapid and efficient response and coordination may mean the difference between life and death, the medical field lags far behind the other emergency services in the development of an integrated system coordinated by a communications network. Indeed, if conditions like those in the medical field existed in law enforcement, it would be considered a major public problem requiring drastic corrective action.

Delays in Gaining Access to the EMS System

Perhaps the weakest link in the whole chain of events in emergency medical care is the detection and reporting of an emergency. Many victims die because

accidents go undetected or unreported (often for lack of a telephone or radio communications) until it is too late. Even when such facilities exist, many die because people do not understand when or how to enter the system.

Entry into the system depends heavily on the telephone, but many communities have no clearly identifiable way, such as a central emergency number, or the public may be unaware of the proper number to call; people often find themselves dealing with physician answering services and crowded switchboards of hospitals and clinics. Even where emergency telephone numbers are designated the system can be confusing and uncoordinated with the result that a medical emergency, though reported, fails to gain proper attention. In one metropolitan area, there are 33 police and 57 fire numbers listed. Roadside telephones are sparsely spaced and difficult to find, even on major highways, and are sometimes infrequent in rural areas. When found, the lack of a dime can mean the difference between life and death!

In many areas, especially rural, reporting is not the ^{only} prob^{lem}. The problem is a basic need for a total EMS system.

Delays in System Response

Once the medical emergency is reported, it must be screened by trained personnel and then aid must be dispatched, usually in the form of an ambulance and crew; but dispatching is often uncoordinated, causing response times to be needlessly slow. Not rarely more or fewer ambulances than necessary arrive at the scene. One reason, in addition to inadequate planning, for the lack of coordination is that there is insufficient communication between ambulances and dispatchers. Only 56 percent of the nation's ambulances have two-way radios; most of these offer communication only between the ambulance and its headquarters, and are concentrated in several of the nation's larger cities.¹⁹

Although there is often a need to coordinate responses among several public safety services (fire, police, ambulance, hospitals), this is rarely possible because of the lack of a central communications point or because each service is limited to its own radio frequencies. Inability to cope with traffic and congested streets, or need to bring in ancillary or back-up services, may cause delay in reaching the patient and transporting him to the hospital.

Lack of Medically Supervised Care at the Site and in Transit

Many patients die unnecessarily on the way to the hospital, when the use of proper stabilization techniques employed at the scene and during transit might have saved their lives. The effectiveness of such techniques -- practiced by well-trained and well-equipped emergency medical technicians, on board the ambulance, with physician direction by means of two-way voice radio--has been ^{11,12,13,14,15,16,20,38,39} well documented, yet few communities in the country have such systems.

Since there is seldom any communication between hospital and ambulances (only 6 percent of the nation's ambulances are so equipped)¹⁹, there is often no way to notify the hospital of the patient's condition or to get medical advice from a doctor, and costly delays can occur when mobilization of necessary staff and equipment must await the arrival of the ambulance at the hospital door.

Distributing Patients

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Without pre-arranged plans for distribution of casualties, without ambulance-hospital communication links, without trained dispatchers, and without inter-hospital communication and coordination, it is customary, once help arrives on the scene, to transport the patient to the nearest hospital,

thus, the community hospital is frequently confronted with patients requiring specialty services and equipment beyond local capabilities, yet it is often these hospitals to which these patients are first taken. Such hospitals, however, must assist in stabilizing the victim before he is transferred to a hospital providing definitive care.

Lack of inter-hospital coordination and communications may also mean an overcrowded emergency department in one hospital while others in the same vicinity stand idly by. Such haphazard and uncoordinated operations of emergency centers and ambulances may mean the loss of valuable time as the patient waits in one hospital's emergency department or is shifted from one hospital to another. Further, the need for triage and a rational distribution of patients among different hospitals becomes vital in a large-scale emergency or disaster when any one hospital could be overwhelmed.

The inability to communicate across jurisdictional lines is another serious obstacle to the provision of good emergency medical care. This can be particularly true in heavily populated areas. In one New Jersey county, an area of about 180 square miles, there are 70 separate towns, each with its own ambulance and police radio frequency, attempting to serve a population of almost a million people. No ambulance can be reached by any but its own police department (because of radio frequency differences), and no ambulance answers calls outside its own jurisdiction except in disasters. Until recently, none of these ambulances was able to communicate with any of the area hospitals. In other areas, frequency differences may make it necessary for the ambulances to carry several radios. This is both cumbersome and costly.

In summary, as emergency medical systems become organized, they will require properly designed and integrated communications networks if they are to provide prompt, efficient, and effective emergency care.

Communications Problems Can Be Solved

When the EMS system has been defined, community commitment and resources determined, and the EMS administration organized, then EMS communications can be planned and implemented, using the systems approach. Consideration must be given to each step of the process, from the moment an emergency occurs to the completion of definitive care. The hospitals, ambulances, and other vehicles, dispatch centers, and all other facilities must be tied together with a coordinated and integrated communications system, with the goal of rapidly rehabilitating the patient.

Many communications problems can be solved by the application of already existing knowledge and techniques. Together with sound organizational procedures and coordination, the efficient use of telecommunications can make entry into the medical care system easier; can reduce dramatically the response time of ambulances and rescue squads, can make possible the immediate provision of medically supervised care at the site of the emergency, can even, in effect, bring the emergency room to the side of the patient, and can ensure that the patient is transported quickly and under medical supervision to the hospital most capable of caring for him. Through communication, specialist teams can be immediately brought together at the hospital, needed supplies can be mobilized, and in the case of disasters, patients can be distributed among a region's hospitals on a rational basis.

Furthermore, improved communications can lead to far more efficient use of physicians, can ensure the most effective use of trained paramedical personnel and emergency medical technicians can provide for long-distance monitoring of patients, can facilitate expansion of services to remote areas and make it easier for doctors to work there, can create efficient and accessible systems for patient medical records to promote more efficient and better patient care, and can make possible uniform methods of data col-

lection for medical audit, quality control, and for

further research and resultant improvements in provision of emergency medical services, and in measures to prevent the need for such services.

GENERAL CONSIDERATIONS IN EMS COMMUNICATIONS

Background

The last decade has seen mounting concern among professional and lay organizations over the need for better emergency medical care. Among those who first gave their attention to the problem were the Committee on Trauma of the American College of Surgeons, the Committee on Cardiopulmonary Resuscitation of the American Heart Association, the Committee on Acute Medicine of the American Society of Anesthesiologists, and the Committee on Injuries of the American Academy of Orthopaedic Surgeons. Since 1966, a number of new groups have been formed, including the Commission on Emergency Medical Services of the American Medical Association, the Committee on Community Emergency Medical Services of the American Medical Association, the American Trauma Society, the University Association of Emergency Medical Services, the American College of Emergency Physicians, the National Registry of Emergency Medical Technicians and others.⁶ In July, 1968, the Midwestern Governors Conference, by resolution, requested "federal assistance in the development of coordinated interlocking telecommunications systems." Hitherto, efforts have been concentrated on training of ambulance and rescue personnel, improving hospital emergency department facilities, defining proper emergency medical care techniques, and establishing equipment standards. With these components in process of development, it is now possible to develop emergency medical systems with communications serving as the central nervous system.

Previous recommendations on communications focus on two-way voice mobile communications, dispatching, disaster communications, a universal emergency telephone number, training for medical dispatchers, community emergency medical councils, comprehensive planning, and other subjects, but often miss the key point that EMS systems planning and a clear definition of the need to communicate must precede action on problems of equipment.^{1,4,5,22,23}

The federal agency most active in behalf of emergency medical communications has been the Department of Transportation (DOT)*. The Highway Safety Act, enacted in 1966, provided the financial and legislative authorization to improve and expand emergency medical services in the states. Subsequently, the National Highway Traffic Safety Administration of the DOT developed state guidelines (Standard 4.4.11) for the provision of emergency medical care as a part of state highway safety programs. Three out of the eight requirements related to communications are (1) that there be criteria for the use of two-way communications, (2) that procedures be created for summoning and dispatching aid, and (3) that there be an up-to-date, comprehensive plan for emergency medical services, including

- A. Facilities and equipment.
- B. Definition of areas of responsibility.
- C. Agreements for mutual support.
- D. Communications systems.

*For the role of other federal agencies in supporting EMS, see Committee on Emergency Services of the Division of Medical Sciences, Roles and Resources of Federal Agencies in Support of Comprehensive Emergency Medical Services, Washington, D.C.: National Academy of Sciences - National Research Council, March, 1972.

A recently published DOT report²⁴ calls for "the many separate function systems (fire, police) to be coordinated into a total-use system with 'cross-talk' capability for the multiple services responding to accidents and other emergencies. Planning should include integration of communications facilities as an integral part of, and not in isolation from or parallel to, other facilities."

DOT has provided assistance in the planning and development of emergency medical services by funding projects, and has supported more than 300 state and local highway safety projects, including several in the area of emergency communications and improved emergency service systems. Its objectives have, for the most part, been to improve those elements of emergency medical services that are directly related to highway safety and transportation

Emergency medical communications planning has also been encouraged within the overall context of the programs and projects supported by the Division of Emergency Health Services (DEHS) of the Public Health Service. This division has served as a clearinghouse for information, provided guidance and assistance to local, state and other federal agencies involved in EMS programs and has sought to stimulate the development of sound planning, training programs, equipment standards, public education and research in the field. More recently, the Health Services and Mental Health Administration, of which DEHS was a part, sponsored the implementation of demonstration EMS systems in several settings across the nation.

The following sections discuss basic principles in emergency medical communications, the functions of the EMS communications system, community organization, and funding.

Basic Communications Principles

This section will summarize basic principles and considerations, a number of which have been stated by one or another of the groups mentioned above, and show how they relate to a total emergency medical system.

Area-Wide EMS Systems

Emergency medical services systems should serve defined populations in circumscribed geographic areas. Such areas usually will contain one or more hospitals of varying capabilities. An objective of such a system is to make the best use of all resources according to the patients' needs. For such a system to be effective, smaller communities and rural areas must be served by the more extensive medical facilities and personnel found only in larger urban areas. At least one hospital in the system should have a complete emergency capability.*

Emergency medical services areas are gradually being defined by local usage, based on patterns of use, types of services and facilities available and the time element involved in the delivery of patients to the hospital. Also relevant are political, geographic, demographic, and other factors. An area may cover a number of counties in a rural state or only a section of a large metropolis such as New York City. Need for arbitration, through state emergency medical councils, may arise when jurisdictions overlap.

Ultimately, as emergency services areas expand, communications must be planned for larger regions (e.g., administrative subdivisions of states,

*Hospital emergency departments in many communities are now being categorized according to their capabilities for providing emergency care; criteria for categorization have been widely publicized. See American Medical Association. Recommendations of the Conference on the Guidelines for the Categorization of Hospital Emergency Capabilities. 1971. Chicago, Ill.

that may contain a number of emergency medical service areas).

Planning for entire states has been urged by the American Medical Association and is being promoted by both the Department of Transportation and the Health Services and Mental Health Administration and others. A number of states such as Nebraska, Illinois, and Colorado, are now in the process of devising state emergency medical communications systems which integrate with those of other emergency public protection systems.²⁵

A recent report of the National Academy of Sciences sums up this requirement: "Full collaboration of the communication systems of multiple political jurisdictions within an emergency medical services area are essential to effective day-to-day emergency care within that area. Integration of multiple areas is essential to optimal response to widespread natural disasters or a national emergency."⁶

Thus:

Emergency medical systems and the communications that support them must be planned on an area-wide basis, irrespective of artificial boundaries or local political jurisdictions. Hospitals and ambulances in one area must be able to communicate with those in neighboring areas.

Coordination with Other Agencies

The EMS system must be viewed as one part of a total community response capability. Also included are law enforcement, fire, public utility, and disaster relief elements. In many routine emergency situations, and always in the event of disasters, a coordinated response by many agencies is required.

Often, however, communications systems are designed for the exclusive use of one agency, with little regard for any of the others. This should not continue:
20, 26

Emergency medical communications must be planned as an integral part of a total community communication network. Conversely, all communications systems planning, like that now being carried on at the state level in many states, should include an EIS communications component.

Universal Emergency Telephone Reporting System

With the universal emergency telephone number (911) system, any standard public telephone can be used to call an emergency response center simply by dialing 9-1-1. Coins are usually not required for pay telephones in the system. Therefore, any citizen, by means of an easily remembered telephone number, can summon immediate aid. The system, which should be used as entrance to all community emergency systems, has obvious advantages which far outweigh the technical problems of implementation. Like other elements of an EIS communications system, it requires organized community planning before it can be implemented.

Such systems are gradually being accepted and established in various parts of the nation; a few hundred jurisdictions now employ this technique. The areas spanned by these current systems cover populations ranging from a few thousand to several million, and the systems have demonstrated their usefulness when coupled with a well-planned and integrated emergency system designed to respond to the full range of emergency calls received.

The commercial telephone system is the largest and most accessible reporting system available. Its effective use must be assured:

The 911 universal emergency telephone reporting system should be implemented on a nationwide basis, and EIS communications systems should provide for its incorporation.

Central Dispatching

Whether in the usual mode of responding to the myriad of daily emergencies or in the unusual mode of dealing with a major calamity, the

coordination of an emergency response is best performed in an area-wide Emergency Communications Center which, for example, receives all 911 telephone, radio, or other emergency calls. Such a system must also have a central point to which all calls requiring medical assistance are immediately transferred. Further, the effective utilization in an emergency response of EMS resources (all hospitals, ambulances, etc. in the system) requires coordination and screening which can best be accomplished at a central control location. Some community-wide systems may have only one such EMS dispatching center; others (e.g. large metropolitan areas) may have several.

The requirement is clear;

Central coordination of the response to a medical emergency, including the central dispatching of all emergency ambulances and other rescue units and single-point coordination with other agencies, is essential to an area-wide EMS system.

Functions of the EMS Communications System

The functions of the emergency medical services communications network are several: (1) to tie together EMS subsystems, thus facilitating patient entry into the system, (2) to assure dispatch of EMS resources to the scene; (3) provide for medically supervised patient care at the scene and at all times while under the management of the EMS; (4) to coordinate transport of the patient to and between treatment facilities, (5) to coordinate the interactions of the various agencies, facilities and manpower within the system; and (6) to coordinate EMS with other public and private services. The communications requirements resulting from these functions can be developed by considering, in turn, the time sequence of events surrounding a medical emergency and the response thereto.

Detection and Reporting

The detection of emergencies, whether by victims or observers, can be increased in effectiveness first by public education to teach each citizen to recognize promptly an emergency, his own or that of others, and second by inculcating in him a strong sense of responsibility to report it immediately.

Once detected, there must be an easy means of reporting the emergency situation. This can be accomplished by the implementation of the universal emergency telephone number (911), by providing telephones where none exist (e.g. in rural areas), by organizing groups of citizens likely to come upon emergencies (e.g. the nation's bus, truck, taxi and public service automotive fleets), and by encouraging the citizen's responsibility through such legal means as good samaritan laws. Where large groups gather, as at sports arenas, or at places of high hazard, EMS facilities, or a "hotline" to an EMS communications center should be established.

Dispatch of Aid

The dispatching of aid involves ambulances, rescue units and qualified medical personnel as required. It also can include police, fire, public utility, tow trucks, and other units. At times of major disasters, heavy construction equipment, food, shelter, and other extraordinary services may also be required.

Standard dispatching technique should require that the driver of the responding vehicle notify the dispatcher of the time of departure to the scene, arrival at the scene, departure from the scene, delays encountered enroute, arrival at a hospital and readiness for another assignment. The times of these actions should be recorded to permit an analysis of the system response effectiveness and for protection against claims of avoidable delay.

In addition to the initial dispatch, the dispatcher should be able to provide routing information to vehicles in transit specifying the quickest route from the standpoint of distance, road conditions and congestion. He also must be able to call ancillary aid from other agencies. Thus, he requires direct or dedicated communication links with the bases -- where ambulances are deployed, with all vehicles by means of two-way voice radio, with all hospitals in the system, and with the emergency response dispatchers of other services such as police, fire, civil defense and public utilities.

Rendering Care at the Scene and in Transit

Of the many improvements which can now be recognized as essential to quality emergency medical care, the provision of treatment by well-trained emergency medical technicians (EMT's) at the scene and during transit to a hospital, under the direction of a remotely-located physician, is one of the most important. Depending on local laws and EMT training, life-saving measures performed by the ambulance EMT under physician direction by radio can include tracheal intubation, defibrillation, intravenous fluid therapy and drug administration. In addition, without physician direction, he can control bleeding and perform standard cardiopulmonary resuscitation measures, splinting, etc..-

This concept of mobile, physician-directed medical care offers much promise for small communities or rural areas where hospital emergency departments and doctors are not constantly available,¹⁴ and where patient transport times can be as long as several hours. In urban areas, although transport times are usually shorter, the capability and procedures for providing physician-directed treatment must be available.

To perform this task, the ambulance EMT's require two-way voice communications with a physician. (A single physician may provide support for more than one ambulance crew). Further, advanced treatment techniques require that the physician have access to physiological data and patient history, as well as the EMT's visual observations of the patient's condition. The electrocardiogram (ECG) is one type of virtually continuous data which needs to be provided to the consulting physician. This requires telemetry communications from the patient (e.g. a portable transmitter) and from the ambulance to the physician. Vital signs such as blood pressure, respiration rate, and pulse can be easily determined by the EMT. He can also be trained to recognize critical ECG patterns for which he can solicit action.

Transportation to the Appropriate Hospital

It is common practice today, particularly in the systems having no two-way ambulance radio communications, for an ambulance to pick up an injured or sick person and deliver him to the nearest hospital, whether or not that hospital is the best one available to treat the specific problem of the patient. In an efficient integrated EMS system, however, the hospital to which the patient is delivered is determined on the basis of the patient's condition and on the capability of the hospital to handle the case. The well-trained emergency medical technician in the ambulance assesses the patient's condition and, using established procedures, consults with the medically trained dispatcher and/or physician, selecting the best destination

for the patient. The dispatcher and the ambulance crew are aided in this decision by prearranged, medically established guidelines; for example, severe head injuries to hospital A, B, or C; apparent cardiac cases to hospital B or D; pediatric cases to hospital E; burn cases to hospital F, etc. It must be recognized that this procedure may be modified by directions from the patient's physician and by hospital capacity at the time.

The procedure requires ambulance-hospital-dispatcher-physician communications links. The dispatcher should be cognizant of the emergency medical capabilities of each hospital in the area, have available up-to-date inventories of hospital bed capacities for emergency admissions, and be able to ascertain blood supplies, types of ancillary equipment available, and other information to aid in the distribution of casualties. Using these communications links, either the dispatcher or the ambulance crew should notify the receiving hospital of the estimated arrival time of the ambulance and provide necessary information, including scaling when available, on the patient's condition to permit initiation of preparatory activities at the hospital when required.

Patient Care in the Hospital

Hospital-to-hospital communications may be used to obtain medical consultation on a patient and to arrange for patient transfers between facilities* when such is dictated. All hospitals in an EMS system must

*It is important that ambulances and hospitals have interchangeable, or compatible monitoring equipment, to ensure continuous monitoring during patient transfer.

have the capability of conferencing on a communications network as well as being able to communicate individually with each other. This conferencing is necessary to coordinate services during large-scale emergencies or at other critical times; for instance, when quantities of a rare blood type are required by one facility. The key role of the hospital in the community emergency response capability also requires that direct communications between the hospital and police, fire and other emergency communications centers be maintained.

Within the hospital, hospital communications systems and physician paging systems as well as "Code Blue"* systems are directly related to and should be made compatible with the emergency medical communications network. The intra-hospital communications system is used to coordinate the transfer of patients from the emergency department to other units within the hospital such as a coronary or intensive care unit, as well as to summon aid to the emergency department when required.

As a minimum then, communications must provide direct, two-way links between emergency vehicles and facilities, between physicians and facilities, between physicians and emergency vehicles, between patient locations, physicians, and facilities using portable equipment, and between and within hospitals.

Community Organization

Most communities have elements of an emergency medical services system in existence and operation, albeit perhaps unorganized and fragmented. The process of organizing and integrating these by means of a communications network

*A system that immediately mobilizes aid within the hospital (personnel and equipment) when a patient in the hospital suffers a crisis such as a heart attack.

does not always begin at the same level. In some places, the planning for emergency medical services and communications has begun at the state or regional level, with the purpose of encouraging local communities to upgrade their own systems by joining the state or regional system. In other places, a particular community has organized and upgraded its own services and communications, with the expectation that this will lead to the up-grading of systems in surrounding areas that may eventually become integrated with it. Also, a local community organization may provide the impetus or starting point for the creation of a broader system.

From whatever source the impetus comes, action is necessary at the local level to assess resources, to determine needs, and to produce the coordination necessary before a local system can become part of a larger network. Each community has its own set of needs and must choose from the alternative communications technologies and systems those that best serve its area. Depending on facilities available, geography, population, subsystems in operation, and other factors, the design of each system will contain unique features.

It is generally agreed that the first step must be the formation of community and state "Emergency Medical Services Councils" composed of providers of emergency services, public and voluntary agency representatives, and community leaders. Active participation and direction by the medical profession is essential. The functions of such councils and guidelines for establishing them have been delineated in publications by the American Medical Association (A^MA),²⁷ the American Society of Anesthesiologists,²⁸ and others.^{29,30}

The first task of the EMS system designers is to conduct an evaluation at state and local levels of the current status of emergency health care. As stated in the A^MA publication cited above, the evaluation should consist of:

"(1) A survey of the people, facilities, and equipment currently rendering such care; and

(2) A survey of the current need for emergency health care."

A part of the survey of existing resources will include an inventory and assessment, with the aid of the best communications expertise available, of currently used communications equipment, facilities, and procedures. The communication systems survey should:

- (1) Determine all EMS communications equipment in use by type, number, frequencies and power (for radio equipment), location, serviceability and age.
- (2) Determine how the equipment is presently employed to detect and report emergencies, dispatch aid and provide for patient care.
- (3) Determine how the agencies within the health care system (hospitals, clinics, ambulance services, neighboring EMS systems, etc.) and other emergency services (police, fire, civil defense, etc.) relate and react to each other, both locally and regionally.

The total inventory of resources, including communications, will be used by the EMS community planning and operating bodies in designing and in initiating implementation of the integrated EMS system and communications network and in educating the public to the need for such a system. Wherever possible, existing resources should be used. At the same time, the system should be built in such a way as to be flexible and compatible both with systems in neighboring areas and with current and future communications planning in the region and state.

The planning and development of the system includes determining needs and comparing alternative ways of meeting them, coordinating with other users and agencies, establishing equipment specifications and procuring it. In these tasks as well as in selecting radio frequencies and applying to the

Federal Communications Commission for frequency assignments,* in fact during the entire systems design and implementation process, the aid of consultants may be required. As a start, the Department of Transportation's recent publication Communications Guidelines for Emergency Medical Services²⁴ and the 1972 HSMHA report, Emergency Medical Services Communications Systems,³⁶ provide comprehensive information on how to set up an emergency medical communications system, detailing each step of the process.

EMS SYSTEMS DESIGN: COMMUNICATIONS ASPECTS

General Design Features

Underlying the design of the entire E&S communications system are certain general design principles. Although some may seem obvious, few systems embody them all:

Accessibility and Speed

Messages must be capable of fast transmission--the system must be accessible to its users and designed to prevent costly delays. Dedicated telephone lines[†] and hot lines[†] (lines reserved solely for a specific use), rather than public telephone service, are required for certain key communications links.

Backup

Essential communications landlines must have radio backup channels in the event of disruption of the primary links. Natural disasters can obliterate telephone and other landlines. Emergency power must be available to operate key equipment in such situations.

Compatibility

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It seems likely that in the future an area-wide system must be compatible with regional, state and national EMS, disaster and other emergency systems, including those planned for future implementation.

*This is discussed more fully in Appendix B.

[†]In the text that follows, technical terms that are more fully explained in Appendix C are so marked.

Continuity

Communications must be available for use on a 24-hour basis. Where stations in the EMS system are not manned continuously (e.g. at a rural clinic or physician's office), provision must be made for alternate communications links to accomplish necessary functions during the off-duty period. Also, there must be redundancy for peak traffic capability as well as for insurance against loss of service at a critical moment.

Convenience of Use

Equipment must be simple enough to be operated easily by non-technical people with a minimum of specific training.

Coverage

The telephone and radio systems must cover the entire geographic area. Repeater stations²² (radio relay devices), microwave backbone systems²³ (a multi-message carrying link between two or more points), and antennas located on mountaintops or high buildings can increase coverage.

Flexibility

The system must be flexible, maintaining the capability for efficient growth consistent with long-range projections of needs and services.

Non-Interference and Frequency Coordination

Radio frequencies must be carefully selected to meet the variety of EMS needs while minimizing the possibility of interference by existing users of nearby channels in the area. Frequency assignments used to communicate with other agencies must be carefully coordinated and made compatible with the agencies' operating frequencies.

Radio Spectrum Management

The competition of all users of radio communications has created an intense demand for frequency assignments with resulting congestion on the airways.²⁴ Thus, radio communications should be used only where other links (e.g., telephone, cable) are inadequate or inefficient. Consistent with effective operations, procedures should encourage minimal use of radio facilities.

²⁴See Appendices A and B for a further discussion of this problem.

Regular Use

All communications facilities, both primary and backup, should be utilized daily to ensure their operational readiness and to keep the staff well aware of their presence and well-versed in their use.

Detection and Reporting Systems.

The 911 System. The installation of a 911 system requires that telephone company personnel be included in state and community planning as early as possible. The Bell Telephone Company has assured the United States Public Health Service (USPHS) Division of Emergency Health Services (DEHS) that its personnel will provide guidance to community groups interested in installing such a system. In the event that local telephone companies are unable to provide necessary information, requests may be referred to the USPHS-DEHS office.

Telephone companies note that 911 systems feeding into area control centers can be tailored to any geographical area, from a small town to an entire state. The point at which telephone trunk lines converge is most important. Local telephone companies are aware of the location of existing trunk lines and can advise if additional ones are required for installing 911 systems. In addition, the Bell Telephone Company holds seminars, in Chicago and New York, covering hospital and medical telephone communications and applications and including the 911 system. They are open to federal, state and local personnel who wish to attend.

A study of existing 911 systems shows that while all are identical as to function (i.e., routing emergency calls to the proper action agency),

many different methods are employed to achieve this goal. In one city, the 911 system terminates in the police dispatching center while another city uses the fire department center; in each case, calls for services not provided by the reception agency are transferred (e.g., to the EMS dispatching center). Other systems terminate in a single emergency communications center from which all emergency resources are controlled.

Key to the success of a 911 system is the operation of the center that processes incoming calls. The greatest problem in implementing the 911 system has been that of what agency answers calls and how they are handled. To quote one study:

"Interagency conflict between police and fire agencies is generally more severe, more emotional, and more disruptive than conflicts or problems between jurisdictions... The key issues in interagency conflict situations (is) the command/control question..."³¹

The conflict noted above can most easily be resolved if there is an independent communications center in which all public safety agencies are integrated. The Committee on Emergency Medical Services of the National Research Council recommends the use of the more than 3,600 Emergency Operating Centers which have been established under the national civil defense program for disasters and major emergencies:³²

"The compatibility of communication facilities of these Centers locally, regionally, and nationally provides a model for the integration of all emergency response systems. They should be activated and utilized on a 24-hour-a-day basis on a national scale. . .⁶

Since, at present, most agencies demand that they dispatch and control their own units, the 911 operator must screen the call and transfer it to the appropriate EMS, police, fire, or other dispatcher. Means of handling non-emergency calls (e.g., by transfer to a "citizen's complaint" center) should also be possible. The 911 operator should remain on the line until a sure connection is made; in this way, misdirected calls and those requiring multi-agency responses can be efficiently accommodated.

Simple, automatic switching arrangements and dedicated hot lines between 911 center and the response agency dispatchers are essential. Backup communication channels also should be provided. Coin telephones should be able to handle 911 calls without the need of a coin, and all public telephones should have an easily-read plaque attached that prominently identifies the phone by an assigned number or by location. The latter permits the 911 operator to quickly identify the location of a caller who is not familiar with the area. Finally, despite the most intensive public education campaign,²⁰ some citizens will still dial "0" in an emergency. Provision must be made for the simple transfer of such calls to the 911 operator.

Alternatives to the 911 system have been used in some cities; a common seven-digit number identified as the emergency number has been used and is an improvement over multiple emergency numbers for police, fire, etc. In widespread areas, particularly in rural regions encompassing many telephone central offices or companies, all of several emergency numbers can go to one exchange, or a toll-free, inbound WATS (Wide Area Telephone Service) system can be used to provide a single-number system. In southeastern Ohio, for example, in a centrally-dispatched EMS system, it is proposed to use an easily remembered WATS number (444-4444) over a seven-county area having many independent telephone companies within it. The only advantage of such systems is that they are easy to install. In the last analysis, they are only stop-gap, the 911 system will ultimately be deployed nationally as it already has been in Great Britain, and elsewhere in Europe.

Vital to any telephone reporting scheme is the distribution and placement of telephones. This is now inadequate in most places. Telephones are scarce on rural roads and are few and far between on major highways. On thruways,

for instance, they are often located only at interchanges that may be many miles apart. Even on city streets, many telephones are not readily available during non-business hours. Although the expense of lining all rural roads with telephones would be prohibitive, as a minimum signs with directions to the nearest phone should be strategically placed at frequent intervals along roads and highways.

Telephone and Signaling Call Boxes

Emergency roadside telephones have been installed on some express highways. On the New York State Northway between Albany and the Canadian border, telephones which connect directly to State Police Centers are placed at half-mile intervals. Some cities have replaced their network of street corner fire alarm boxes with telephones connecting directly to an emergency center, prepared to respond to emergencies of all types, often resulting in a great reduction in false alarms.

Emergency signal-emitting call boxes (a system this committee does not recommend) have been installed at closely-spaced intervals on sections of Interstate Highway 495 around Washington, D C. The call boxes are available with push-button signals for "Police," "Maintenance," and "Fire." The words "Health," "Medical," or "Ambulance" are not used but could be. The absence of voice communications, while permitting less costly installation, creates problems. No description of the emergency is available to the signal-receiving center; a police car is dispatched to the call box location to ascertain the nature of the situation. Further, the lack of feedback to the motorist that his signal has been received, coupled with the impersonal nature of the non-voice system, greatly increases the false alarm rate, the Interstate 495 call boxes generate a 30-percent false alarm rate, while the New York Northway system experiences only a 7-percent rate.

False Alarms. The false alarm problem in detection and reporting systems is significant and merits special attention. With appropriate technology and procedures, the use of telephones in lieu of signal call boxes can greatly reduce the problem.

The following is recommended:

- (1) Place automatic tape recording equipment and beepers on all incoming emergency call lines and widely advertise that all calls are recorded.
- (2) When a false alarm is suspected, the calling number should be called back for confirmation. If a true calling number had been given to the dispatcher, the call is nearly always legitimate.
- (3) Utilize the telephone company's "locking-in" equipment that prevents the call from being disconnected, even when the caller hangs up, thus permitting tracing. Advertise widely that this procedure is used.
- (4) If the problem proves to be serious, consult the telephone company for assistance in identifying the sources of the false alarms.
- (5) Promote legislation of stiff penalties for perpetration of false alarms.

There has been much publicity about voice prints and sound spectrograms as a means of speaker identification or lie (false alarm) detection. However, scientists at present have reservations about their real value and more research is needed before they will be acceptable as a means for eliminating false alarms. On the other hand, publicity about use of voice printing in the system has had the effect, in some areas, of greatly reducing false alarms.

Utilization of Citizens' Groups. There have been several attempts to make better use of various citizens' groups in detecting and reporting emergencies. Perhaps the most successful is the Radio Amateur Civil Emergency Services (RACES),* which formally organizes "ham" radio operators under local civil authorities to provide communications during civil emergencies or

disasters. Some 22 frequency bands are available for this purpose.

To make full use of the RACES system in the event of disaster, EMS planners should coordinate communications plans with local amateur groups and civil defense units. In addition since many amateurs have mobile radios in their cars, a means should be arranged to receive their radio emergency calls at the EMS communications center and to make them a part of the daily emergency reporting system.

Another effort has been the organization of the users of Channel 9 of the Citizens Band (27.065 MHz), designated by the FCC for motorist assistance and emergency use only. A nationwide volunteer organization of Citizens Band users, REACT,⁺ claims 40,000 members who are organized in about 1,000 local teams that monitor the channel regularly and report emergencies to the appropriate agencies by telephone. The usefulness of Channel 9 for emergency medical communications is limited, however, by the extremely large class of licensees among whom its use must be shared, technical problems such as "skip interference,"^{*} the limited transmitter power permitted (5 watts), and the lack of protection from interference by licensees who misuse the channel. Proper use of the channel is difficult to enforce, and licensees are not tested for their competence.⁺⁺

The nation's bus, truck, taxi and public service fleets represent a valuable resource. There are over 100 million air and land carrier vehicles. Provided with the proper radio-telephone links, they could enhance considerably the effectiveness of the detection and reporting system. Many of these already are equipped with two-way radio communications. Again, voluntary groups

⁺Radio Emergency Action Communication Team, 205 West Wacker Drive, Chicago, Illinois 60606.

^{*}See Appendix A.

⁺⁺Also see the discussion of the Citizens Radio Service in Appendix B.

are attempting this. "Community Radio Watch" is a user's group established by one major supplier of mobile transceiving equipment. Every user of two-way radio equipment is requested to be alert for and to report emergencies to his dispatcher. However, this potential should not be left to chance. These groups should be organized and provided with standardized procedures for reporting emergencies.

Two elements are essential for these concepts to be effectively implemented: (1) The users must be trained to use the system properly and only for life- or property-threatening emergencies, and (2) a reporting procedure must be established which is equipped to channel the various types of emergency calls to the proper response agencies quickly and efficiently.

Advanced Detection Technology. Other advanced technology detection and reporting devices have been proposed or experimentally implemented. They include such things as continuous closed-circuit television surveillance of streets and critical highway locations (Detroit expressways are so monitored), impact-triggered radio beacons mounted on automobiles which would both notify authorities of an accident and provide a homing signal to locate it, and aircraft and satellite surveillance systems. The "Sender Medallion," a device worn around the neck and activated by slight pressure, sends a low-power radio signal to a telephone attachment which, in turn, alerts a central office through a special telephone line* or radio circuit.

In general, such systems are destined for the future, as yet, they are not well enough accepted by the public for serious consideration today.

*The Sender concept is currently undergoing an evaluation by Medical Emergency Alert, Inc., New York City.

The sections that follow discuss detailed means by which each of the communications links in an EMS system can be provided. While specific recommendations and the use of many examples are made to clearly illustrate basic concepts, it should be remembered that each EMS system has different requirements and will evolve in a unique fashion. No attempt is made here to prescribe a rigid form for the communications network. The design of actual systems must be left to those in the field responsible for it; the recommendations presented below will, in all likelihood, require modifications to fit particular situations.

Dispatcher Communications

This section describes the means by which an EMS central dispatching post can fulfill its various functions.

Dispatcher-Ambulance Communications. The central dispatcher requires two-way radio communications or radio-telephone connections with all ambulances under his control as well as the ability to link with the systems of other agencies. Some systems use simplex[#] (single frequency) and others use duplex[#] (two frequencies) transmission modes; whether operating in simplex or duplex modes, many have at least two channels available for both base station[#] (the dispatcher's location) and mobile (ambulance) transmissions. When vehicles are dispatched by police or fire departments, channels different from those used for police or fire unit dispatching should be used for ambulance communications. Normal police or fire dispatching frequencies can also be provided, however, as backup channels on the mobile units. This also permits coordination of multi-unit responses. In any system, a radio-telephone patch can be used to obviate the need for a third party relay.

Frequencies for centrally-dispatched EMS vehicles equipped with telemetry are available in the ultra-high frequency (UHF) band.*³³ For non-telemetry equipped ambulances, very high frequency (VHF) band* frequencies can be used. However, the trend is toward use of the UHF frequencies, particularly since telemetry is a desirable component of quality service where physician advice is used.* Frequencies used for dispatching should be different from those used for ambulance-physician communications.

Where ambulances are based at fixed locations (e.g. hospitals or fire stations), the dispatcher can make the initial dispatch over a dedicated hot line, regular telephone, or radio. Where hot lines are used (to reduce the radio communication channel load), the ambulance radio provides a backup capability.

Dispatcher-Hospital Communications. The Emergency Department of every hospital used to provide emergency service in the dispatcher's area must be linked to the dispatcher by communication channels. Either hot lines or radio can be used as the primary means of communication. The former is preferred where the cost is not too great. However, radio links must be provided as a backup; channels used for ambulance-hospital communications can be used for this purpose.

Other Dispatcher Communications Links. The dispatcher must be located in or have hot line communications and radio backup with the Emergency Communications Center (911 reception center) where used, as well as with police,

*Appendix A provides an elementary description of these terms, along with a discussion of the differing radio transmission characteristics of the various bands. Appendix B provides details on the frequencies available for use in EMS operations.

fire, rescue and civil defense dispatching centers. Hot lines connections to the medical service or all-service switchboard and to the nearest poison control center are also essential. Further, the dispatcher should be able to communicate with dispatchers of neighboring systems and with regional, state and national emergency authorities. Public telephone service suffices for a primary mode, with radio as a backup.

Dispatching Equipment. Table 1 shows, by example, one way in which a dispatcher's primary and backup communications links could be set up. The example shown utilizes UHF channels for primary ambulance dispatching; a VHF channel (155.340 MHz) is suggested as an area backup frequency used for dispatching and for dispatcher-hospital and hospital-hospital backup modes as well. Another VHF frequency (155.280 MHz) is suggested for regional communications backup.

Telephone-radio, telephone-telephone, and radio-radio patching,[#] permitting the dispatcher to link any of his communications channels together, should also be provided. Where critical links are involved and radio is not an appropriate backup mode (e.g. from the 911 operator to the EMS dispatcher), alternate-path hot lines can be used. Hot lines can be made more secure by such methods as using underground conduit, the telephone companies can provide advice on this and other procedures. The numerous hot lines to the dispatcher do not require separate telephone handsets. One "call-director" unit can conveniently provide all hot line and public telephone connections.

With the half-duplex dispatching system used in the example, where the dispatcher base station is on one frequency and ambulance mobile units on another, tone- or digital-encoded squelch[#] to selectively address the mobile units is not essential. In fact, an advantage accrues from having all ambulances monitor all of the dispatcher's messages, at times a moving

Communication Link	Primary Mode and Typical Frequencies	Backup Mode and Typical Frequencies
To Ambulance - Channel 1 Channel 2	UHF Radio - 460.525 MHz UHF Radio - 460.550 MHz	VHF Radio - 155.340 MHz
From Ambulance - Channel 1 Channel 2	UHF Radio - 465.525 MHz UHF Radio - 465.525 MHz	VHF Radio - 155.340 MHz
Hospitals	Hot Line	VHF Radio - 155.340 MHz
Police, Fire & Rescue Dispatchers	Hot Line	VHF Radio - Police, Fire or Rescue Frequency
911 Operator	- Hot Line -	Alternate-Path Hot Line
Regional EMS Center	Public Telephone	VHF Radio - 155.280 MHz
Neighboring EMS Dispatcher	Public Telephone	VHF Radio - 155.340 MHz
Poison Control Center	Hot Line	Public Telephone
Civil Defense Center	Hot Line	VHF Radio, CD Frequency
Physician	Hot Line to Paging System or VHF Radio	Public Telephone

Table 1

EMS Area-Wide Dispatcher Communications -- An Example

ambulance whose precise location is not known by the dispatcher might be in a better position to respond to a call than the ambulance dispatched by the center. However, for the VHF area backup frequency in the example, where one simplex frequency is used by many stations (hospitals, ambulances, dispatch centers, and others), a tone- or digital-encoded quelch system would be very valuable.

To be able subsequently to evaluate system effectiveness, as well as for legal protection, all communications (including EMT-physician conversations) should be tape-recorded.

Dispatcher Location. The central dispatching office can be located in a variety of places: in a special center, in a major hospital, or within the community's police or fire dispatching facilities. Since a fire department gets far fewer emergency calls than the police, a number of communities have found this to be the best location. As noted above, the Emergency Operating Centers (EOC's) of the civil defense system should be considered as potential sites, particularly for the integration of all emergency communications in small communities. These centers have been established throughout the nation, many with sophisticated communications equipment installed and unused. Also, matching funds may be available for additional equipment and maintenance.

Dispatcher Training. It is important that the staff performing the dispatching and communications functions be properly trained.³⁴ Training requirements should encompass three levels of competency:

- A. General communications skills, including (1) vocal clarity; (2) ear training; (3) equipment operation involving transmitters, receivers, patching systems and (where used), fotofax video system, teletype and computer terminal equipment; (4) EMS system interrelationships; (5) local and state interrelationships; and (6) communication procedures.

- B. Emergency resource operator skills, including (1) all general communication skills, (2) a thorough knowledge of all emergency services available, and (3) medical terminology including training as an emergency medical technician.
- C. Communication supervisor skills, including (1) all general communications and emergency resource operator skills, and (2) interstate and national relationships including military and nonmilitary governmental communications.

Because the dispatcher participates in emergency care decisions, at least one dispatcher on duty should be trained through level B. Further, dispatchers who are not recruited from the cadre of ambulance EMT's should be given considerable experience riding as observers on the system's ambulances.

Physical requirements for the staff are minimal, however, a stable personality and good judgment are required because of the inherent stresses of the environment and the assigned functions. The blind, multiple amputees, paraplegics, or otherwise handicapped individuals are potentially good candidates. In some areas, bilingual ability may be needed.

HOSPITAL COMMUNICATIONS

The hospital emergency department, the focal point of emergency medical care within a community, must be able to be directly involved in all communications systems when an emergency exists outside the hospital.

Communications Coordination. Hospitals must require communications links with the dispatcher (discussed above), with ambulances, with other emergency services (e.g., police, fire, rescue and civil defense), with other hospitals, and with regional EMS authorities.

Emergency Department. The emergency telephone and radio systems must have terminals in the emergency department and, in case the emergency department

is not manned continually, the switchboard should be prepared to assume the responsibility, but with a parallel hook-up. It should be borne in mind, however, that most hospital switchboards are over-loaded and emergency service frequently ranks far down on the action list. Emergency department radios should be on a 24-hour per day operation schedule, for the purpose of monitoring.

Small Community Hospitals. In small hospitals where physicians are not stationed in hospitals the only way of using "on call" physicians is by a mobile-to-mobile operation. The physician "on call" must carry the necessary transceiver equipment so that he, rather than the hospital, may screen, diagnose and prescribe, and administer for the patient's needs. Thus, any frequency allocation should take into account the need for mobile to-base, base-to-mobile, and mobile-to-mobile communications, in order to be fully effective in a small community.

Hospital redline telephone systems and radio systems must have the capability to handle messages for "conference" with one, a few, or all physicians and hospitals in the net. This permits rapid notification of professional personnel and hospitals as needed for coordination and distribution of patients in large scale disasters or on routing of the patients in case the nearest emergency department is overloaded. Although ambulance-hospital radio communication is used only about five percent of the time, the capability is needed. Radio channels used by the hospital for primary emergency care should be different from those used for inter-hospital or hospital administrative purposes, although the administrative frequencies could provide the necessary emergency communications backup.

Hospital-Ambulance Communications. For notification of the impending arrival of a patient, a direct ambulance-hospital radio link can be used or alternatively, direct communications could be achieved by having the dispatcher patch the ambulance dispatch channel into the hospital hot line. An advantage of the latter is that it reduces the need for radio equipment at the hospital.

Where medical direction is obtained from hospital-based physicians, similar methods (direct transmission or patching) can be used to permit two-way voice communication between ambulance EMT's and hospital physicians. However, to provide ECG telemetry displays at the hospital using a patch at the dispatch center, special (but not costly) coupling equipment is needed at both the dispatching and hospital ends of the hot line.

In some places (e.g. Miami, Florida), this method of using medical consultation has been beneficially extended beyond the Emergency Department-based physician. There, portable telemetry readout equipment and portable two-way voice transceivers are provided other senior physicians and specialists who can thus monitor EMT-hospital transmissions and provide additional medical advice when deemed prudent.

For telemetry and telemetry-related voice (e.g. physician direction), the FCC has set aside five UHF dual-frequency channels. In special circumstances, two UHF mobile dispatch frequencies (465.525 and 465.550 MHz) can be used for telemetry purposes.* These channels should be available for mobile-to-base, base-to-mobile, and mobile-to-mobile operation.

* The use of these seven UHF telemetry channels is fully discussed in Appendix B.

Often, the ambulance EMT's stabilize a patient where he lies. In such situations, portable UHF telemetry equipment and portable two-way voice transceivers are used. Because these units are often low-powered, an additional ambulance radio is sometimes used as a relay. FCC frequency authorizations make such use convenient, as they allow the portable telemetry units to operate on the base station frequencies. Figure 1 illustrates this use.

In addition to using direct or dispatcher-patched links, hospitals and ambulances should be equipped with at least one backup radio channel. The area-wide frequency (e.g. 155.340 MHz) recommended above for dispatching backup would be satisfactory.

Hospital-Hospital Communications. The primary mode can be either the public telephone or a hot line circuit patched at the EMS dispatch center. The public telephone mode should be used only where direct dialing from Emergency Department to Emergency Department is available; hospital switchboards can cause unacceptable delays. Again, a VHF radio channel is recommended for backup, with tone- or digital-encoded squelch a definite advantage.

Communications links with Police, Fire, Rescue, Civil Defense, and Regional EMS Centers should (as a minimal essential) be provided in the same manner: by public telephone, by direct hot lines or by patching at the EMS dispatching center

When mobile units (ambulances, helicopters, etc.) interact directly with hospitals, it is essential that each hospital and each vehicle have compatible communications equipment, operating (in the case of radios) on frequencies that have been chosen to meet coordinated EMS system requirements. Further, telemetry equipment (e.g. ECG transmitters) must be standardized in the system so that the patient monitoring function can be

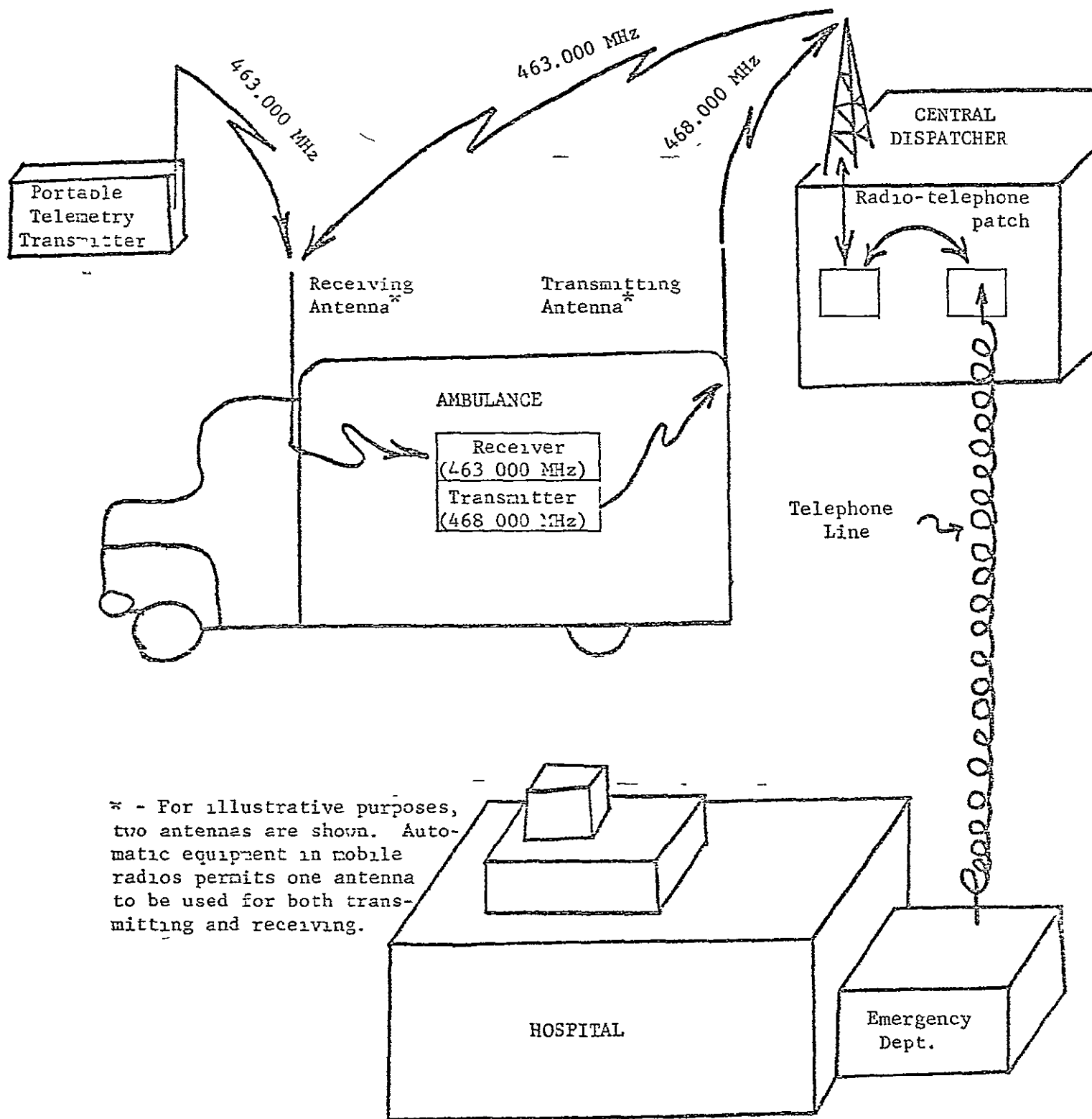


Figure 1 - Portable Telemetry Radio Links

maintained during transfer of the patient from ambulance to emergency department and between services (e.g., emergency department to coronary care unit) within the hospital. At most, it should be possible simply to unplug the ECG monitoring equipment from the ambulance transmitter and plug it into an emergency department monitoring system.

Similarly, no hospital paging of any sort should be permitted on any frequency used by another discipline. Thus, present paging on a shared frequency should be eliminated as soon as possible and not after interference arises. Where existing radio frequencies interfere with local law enforcement or any other SER operation, cooperating arrangements with corresponding agencies must be settled. The same policy should apply for radio tones used for coding and decoding in medical emergencies. Equipment such as this, which remains attached to the patient after transfer from the ambulance must, obviously, be interchangeable throughout the system. Spares should be available at the hospital to replace the unit on the ambulance that was left with the patient.

Table 2 illustrates a possible set of communications channels for hospitals.

Intrahospital Communications. A significant number of medical emergencies occur within a hospital. A command system of communication must be available for the hospital to mobilize specialty teams, equipment, or supplies for both interior and exterior emergencies. This system involves the emergency department, the intensive care unit, and patients' rooms

In a previous section, mention was made of a telemeter EKG monitoring system involving compatibility of the equipment being used in the emergency department (ED) and the coronary care unit (CCU) with that on the ambulance and in other hospitals. Such wireless monitoring equipment has additional advantages for cardiac emergencies arising in the hospital itself. One monitoring screen (or more in large, busy institutions) in the CCU can be

reserved for emergency. Whenever a cardiac emergency arises in the hospital, the CCU is called by phone, this unit is turned on, and the patient is wired with the coupling nodule and appropriate equipment. As treatment proceeds at the scene of the emergency, the CCU is in a position to provide consultative advice and to monitor the patient as he is transferred to it after stabilization.

Special Physician Communications

Special provision for physician communication links must be made when systems do not use hospital-based physicians for medical direction. In particular, rural areas present a challenge. There, securing a physician's consultation might require contacting a physician who can be many miles from the hospital, ambulance, or dispatching center. As already demonstrated in Miami and noted above, such a physician can be given a portable tuned "walkie-talkie" to communicate with the dispatcher. By means of radio-radio patching (or telephone-radio patching if a telephone is easily accessible to the doctor), the ambulance and the physician can be placed in direct contact through the dispatcher.

Where the dispatcher is responsible for securing physicians for consultations with ambulance, rescue unit, or other physicians, hot lines to a physician's paging service, direct control of a paging transmitter, or radio channels monitored by the consulting physicians must be available to the dispatcher.

Another technique found to be valuable in urban as well as rural areas is providing the physicians used for medical direction with portable radios operating on the dispatcher-ambulance frequencies.

Communication Link	Primary Mode and Typical Frequencies	Backup Mode and Typical Frequencies
To Ambulance - Channel 1 Channel 2	UHF Radio - 460.525 MHz UHF Radio - 460.550 MHz	VHF Radio - 155.340 MHz
From Ambulance - Channel 1 Channel 2	UHF Radio - 465.525 MHz UHF Radio - 465.525 MHz	VHF Radio - 155.340 MHz
Hospitals	Hot Line	VHF Radio - 155.340 MHz
Police, Fire & Rescue Dispatchers	Hot Line	VHF Radio - Police, Fire or Rescue Frequency
911 Operator	Hot Line	Alternate-Path Hot Line
Regional EMS Center	Public Telephone	VHF Radio - 155.280 MHz
Neighboring EMS Dispatcher	Public Telephone	VHF Radio - 155.340 MHz
Poison Control Center	Hot Line	Public Telephone
Civil Defense Center	Hot Line	VHF Radio, CD Frequency
Physician --	Hot Line to Paging System or VHF Radio	155.280 or 155.400 Public Telephone

Table 1

EMS Area-Wide Dispatcher Communications -- An Example

A Typical System

To illustrate how all of the links can be brought together in an EMS communications system, a description of a hypothetical system is provided. The examples used in the preceding text are incorporated.

The model, shown in Figures 2 and 3 and Table 4, incorporates the following features:

- o A statewide hierarchical network with a state EMS coordination center, regional EMS coordination centers and area-wide EMS central dispatching centers.
- o A statewide microwave backbone loop[#] connecting all regions.
- o A regional VHF backup radio channel (155.280 MHz).
- o An area VHF backup channel (155.340 MHz).
- o Backup facilities for all other links.

Microwave Backbone Loop.[#] The microwave backbone loop is a broadband[#] point-to-point system capable of carrying many messages simultaneously. Some states (e.g. Nebraska, Colorado) are implementing statewide microwave nets to meet many state communications needs -- law enforcement, public utilities, and public education television, to mention a few. The EMS system can make efficient use of such a loop in some situations.

In some regions (e.g. San Diego County), local governments covering large geographic areas also use microwave nets in a similar fashion. In at least one place in the nation (a seven-county area in southeastern Ohio), a microwave backbone net is under construction specifically for area-wide EMS communications. A Nebraska "test bed" system in the two 12-county areas, consolidating state and local government emergency telecommunications, has drawn national attention as an exemplary system. Those responsible for this system have done considerable research into cross-frequency connections and all-service call capabilities,

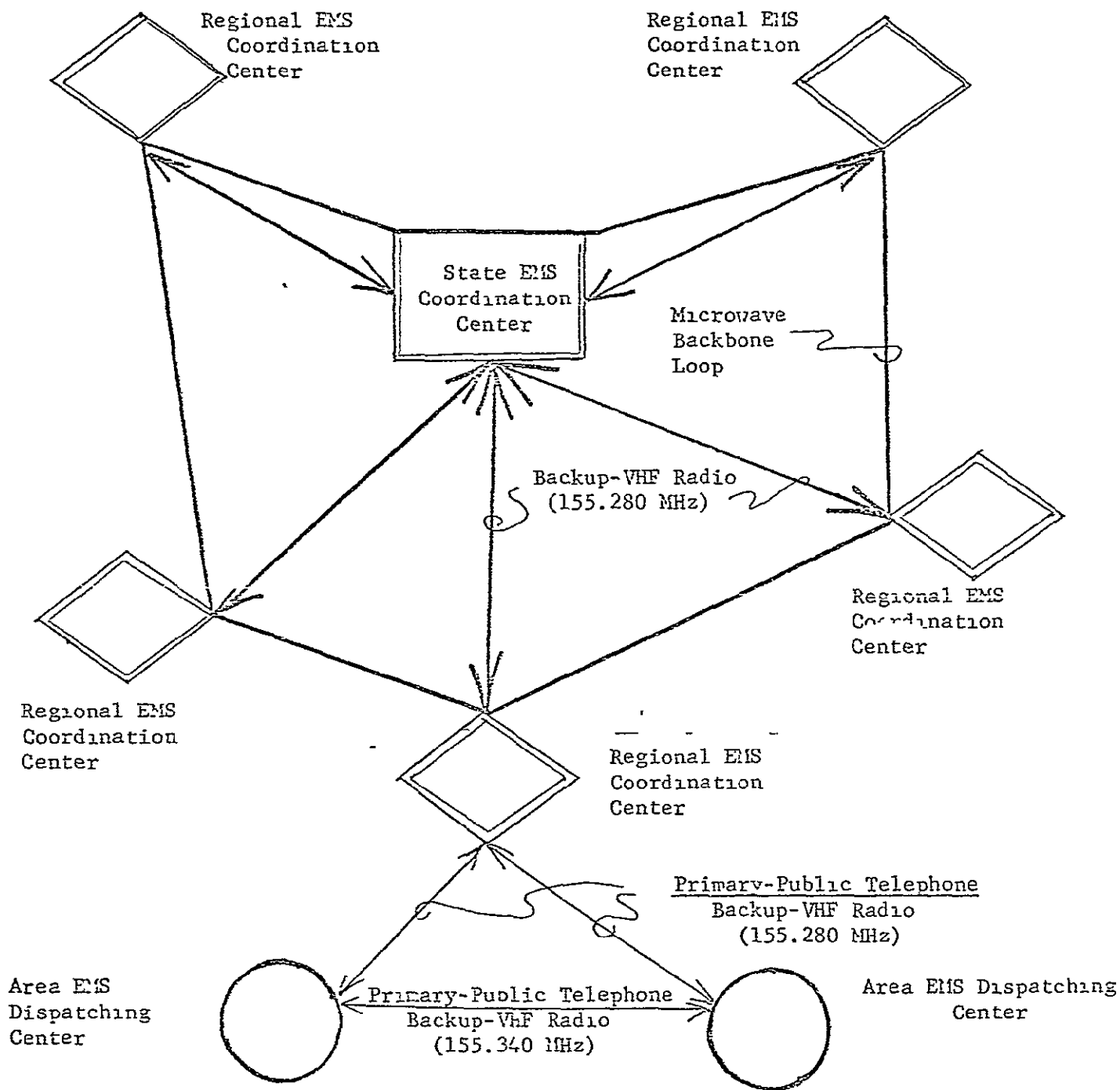


Figure 2 - An Example of State-Wide EMS Communication System



	Transmit	Receive	Use
<u>Ambulance</u>			
1. UHF Radio - Channel 1	465.525 MHz	460.525 MHz	Dispatch
- Channel 2	465.550 MHz	460.550 MHz	Dispatch
- Channel 3	468.000 MHz	463.000 MHz	Telemetry
- Channel 4	468.050 MHz	463.050 MHz	Telemetry
2. VHF Radio - Channel 1	155.340 MHz	155.340 MHz	Area Backup
- Channel 2	155.280 MHz	155.280 MHz	Region Backup
<u>Hospital</u>			
1. VHF Radio - Channel 1	155.340 MHz	155.340 MHz	Area Backup
- Channel 2	155.280 MHz	155.280 MHz	Region Backup
- Channel 3	155.400 MHz	155.400 MHz	Paging
<u>Area-Wide Dispatch Ctr.</u>			
1. UHF Radio - Channel 1	460.525 MHz	465.525 MHz	Dispatch
- Channel 2	460.550 MHz	465.550 MHz	Dispatch
- Channel 3	463.000 MHz	468.000 MHz	Telemetry
- Channel 4	463.050 MHz	468.050 MHz	Telemetry
2. VHF Radio - Channel 1	155.340 MHz	155.340 MHz	Area Backup
- Channel 2	155.280 MHz	155.280 MHz	Region Backup
- Channel 3	155.400 MHz	155.400 MHz	Paging
- Channel 4	CD Freq.	CD Freq.	CD Backup
- Channel 5	Police Freq.	Police Freq.	Police Backup
- Channel 6	Fire Freq.	Fire Freq.	Fire Backup
- Channels 7-8		Spares	

Table 4

Sample System Radio Complements

Microwave transmissions are in the gigahertz region of the radio spectrum and are strictly line-of-sight. Thus, a loop requires antennas strategically located on high towers, tall buildings, or mountain-tops. Connections between the antenna locations of the microwave loop (where entry to the loop is made) and communications points (hospitals, dispatch centers, etc.) can be by cable, dedicated telephone line,[#] or by a short radio link operating in the VHF or UHF band. In a like manner, mobile units (e.g. ambulances) gain access to the loop by communicating with the microwave stations on their UHF or VHF radios.

Although initial investments for microwave equipment are relatively high, state-of-the-art systems (i.e. using solid-state circuits rather than radio tubes) are reliable and inexpensive to operate. Also, cost sharing of the various users reduces the cost to each.

Area-Wide Coverage. As further discussed in Appendix A, radio transmissions have a useful range of about 30 miles or less for VHF and about 15 miles or less for UHF systems. The range can be increased somewhat with tall antennas. Nevertheless, in area-wide systems the need often exists for several repeater stations, properly located, to guarantee complete coverage for the mobile ambulance units. In cities, as well, buildings, highway underpasses, etc., create dead spots that can be removed by repeaters.

It is therefore important to conduct a communications survey of the area during preliminary design stages of the system. Such a study, which can be performed by state or local government communications specialists or by private firms which specialize in radio communications consulting, will help determine the proper radio bands and antenna locations for the system.

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APPENDIX A

RADIO SYSTEM. EXPLANATORY NOTES

Since 1898, when electromagnetic waves were first used commercially, communications via "radio waves" have so expanded that now approximately nine million fixed and mobile radio transmitters are in the United States alone.

Radio waves are a valuable public resource, but technical limitations restrict the quantity of information that can be transmitted through the air on given frequencies (or on given radio "waves") in any given geographical area. Thus, it has been necessary to regulate use of radio frequencies in the public interest. (See Appendix B for an explanation of frequency use and regulation by the Federal Communications Commission.)

Radio Waves

Radio waves are electromagnetic energy radiated into space and are classified according to their length and their frequency. In the diagram below (see Figure #1) wave length is indicated by the space between vibrations (from crest to crest). Amplitude is measured by the magnitude of the vibrations or distance of the wave crest above or below the zero level indicated by the dotted line. Frequency is the number of impulses or complete cycles that pass a given point within a fixed period of time and is measured in cycles per second, called "hertz."

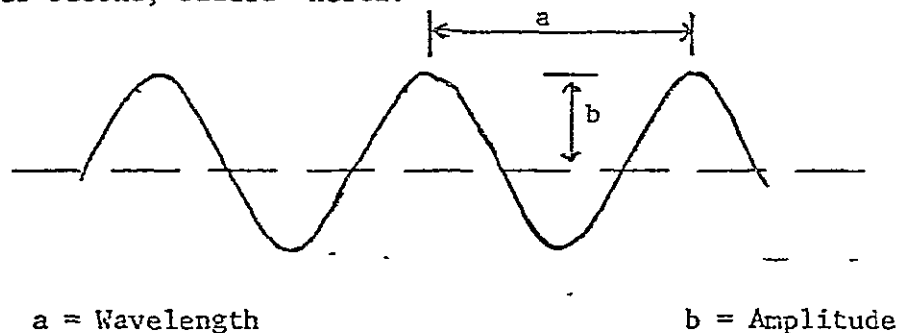


Figure 1 - An Electromagnetic Wave

A kilohertz (kHz) is equal to 1,000 hertz; a megahertz (MHz) is 1,000 kilohertz; a gigahertz (GHz) is 1,000 megahertz; and a terahertz (THz) is 1,000 gigahertz. The entire range of frequencies for electromagnetic waves is known as the electromagnetic spectrum. Radio waves occupy that part of the spectrum from about 3 kHz to approximately 3,000 GHz. Above these frequencies are the infrared (heat) waves, visible light rays, ultra violet waves, x-rays, gamma rays, and finally cosmic rays. Frequencies below 3 kHz are not efficient for transmitting radio waves through space. They are used, however, for the transportation of electrical energy through conductors; for example, the 60 hertz alternating current used in our electrical power distribution systems.

Since electromagnetic waves propagate at a constant speed of approximately 186,000 miles per second, the wave length of any radio emission is inversely proportional to its frequency. The waves at the bottom of the spectrum (lowest frequencies) are the longest, more than 10,000 meters long. They become progressively shorter at higher frequencies, graduating upwards to "short waves," and microwaves of less than one centimeter in the gigahertz range.

The Radio Frequency Spectrum

The radio* frequency portion of the spectrum is divided into bands as shown in the following table.

*Radio is used here in the all-inclusive sense including television as well as other broadcasting and non-broadcasting uses.

Table 1. Radio Spectrum Frequency Bands

Band — designations	Frequency	Wave Length
VLF (very low)	3-30 kHz	Above 10,000 M
LF (low)	30-300 kHz	10,000 M - 1,000 M
MF (medium)	300-3,000 kHz	1,000 - 100 M
HF (high)	3-30 MHz	100 - 10 M
VHF (very high)	30-300 MHz	10 - 1 M
UHF (ultra high)	300-3,000 MHz	100 cm - 10 cm
SHF (super high)	3-30 GHz	10 - 1 cm
EHF (extremely high)	30-300 GHz	Below 1 cm
.	300-3,000 GHz	
	3 THz	

Within each of these large bands, the Federal Communications Commission (FCC) has designated smaller portions or bands of frequencies for different purposes and different users. Besides the bands for AM, FM, and television broadcasting, there are bands for aviation and marine uses, for public safety (police, fire, forestry, local government conservation, etc.) for industrial uses, for land transportation, and for amateur radio operations, among others.

Radio Channels

As discussed more fully below, it usually requires a set of frequencies at least several kHz in width to transmit a message. Thus, bands are divided into channels, portions of the band assigned for a particular kind of transmission by a particular user. A channel is generally designated by its center frequency called the "carrier" frequency. Channels vary in band width in accordance with the intended use and location in the radio spectrum. AM stations in the broadcast bands are separated by only ten kHz. In the higher ranges, assigned channels often have a wider separation to avoid interference and to accommodate the transmission of larger quantities of information. For instance, frequency allocations in the VHF band are spaced at least 15 kHz apart. FM broadcasting requires a wider band than AM, 200 KHz or 20 times that required for AM, and television transmissions require 600 times the space required for AM. Thus, we often speak of "broad band" and "narrow band" transmission.

One channel may also include more than one frequency allocation. For example, paired frequencies may be designated as one channel to provide two-way communication between two points, although the two frequencies are fairly widely separated (for example, by 5 MHz or more in the UHF region). On the other hand, one radio frequency channel may be assigned to a number of different radio stations, so long as assignments are in different geographic areas and do not interfere with each other.

For example, the frequencies 460.525 and 465.525 MHz in the UHF band are allocated for two-way communication between ambulances and dispatchers, and are considered to be one duplex channel. Another frequency, 155.280 MHz (one of the VHF Special Emergency Radio frequencies), may be used in one area for dispatching ambulances, in another for communications between hospitals, and in yet another for school bus communications. These are different "communication channels."

Modulation

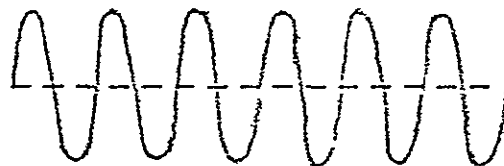
Messages are transmitted by varying either the amplitude or the frequency of the central carrier wave. This coding process is called modulation. Thus, one part of a radio transmitter is a "modulator" that codes the message information into the carrier frequency. A radio receiver has a "demodulator" that analyzes the modulated carrier frequency to permit the information received to be converted into another form--sound, printed facsimile, an EKG wave form on an oscilloscope, etc.

Since often only a part of the radio spectrum width allowed for a channel is needed for a particular kind of transmission (about 3,000 hertz are required for normal voice transmission, for instance), there may also be room in the channel's bandwidth for a "subcarrier." A subcarrier may be used to relay additional information in the same channel for various purposes, for example, telemetering an electrocardiogram signal or for special signals to activate one of a set of receivers all tuned to the same channel, "tone-coded squelch" mechanism.)

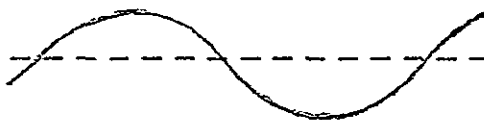
Virtually all the communications equipment offered today by the several manufacturers for land mobile use is frequency modulated. Frequency modulation (FM) techniques provide superior rejection to random noise, interference, and fading when compared to the conventional amplitude modulation (AM) systems. In frequency modulation, the frequency of the "carrier" is modulated by shifting it about its central frequency at the same rate as the intelligence being transmitted. Thus, if the sound "ah-h-h" in speech has a frequency or tone corresponding to 600 cycles per second, the 600-cycle pattern can be superimposed on that of the high frequency carrier wave (say 155.340 MHz) causing the carrier wave to shift above and below its center frequency at a 600-cycle rate (Figure 2).

In both amplitude modulation (AM) and frequency modulation (FM), a modulating frequency, that of the intelligence being transmitted, is imposed upon a carrier frequency. In AM, the modulating frequency causes variations in the amplitude of the carrier (in which the frequency remains constant), in FM, the modulating frequency causes the carrier to shift in frequency within a narrow range.

Unmodulated high frequency
carrier wave
(e.g. 30 MHz)



Modulating signal
(e.g. 600 Hz)



Frequency-modulated
wave about the central
carrier frequency

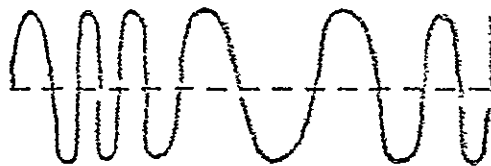
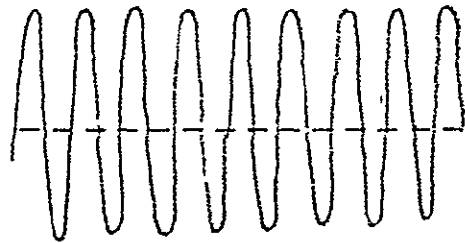


Figure 2 - Frequency Modulation

Unmodulated high frequency
carrier wave
(e.g. 3,000 kHz)



Modulating signal
(e.g. 600 Hz)



Amplitude-modulated
carrier wave
(e.g. 3,000 kHz)

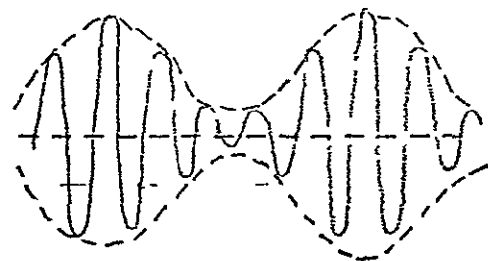


Figure 3 - Amplitude Modulation

Since an outside noise pulse can add amplitude to that of the carrier wave but can have almost no effect upon its frequency, the disruptive effects of noise can be almost completely eliminated in the FM system. This explains why FM systems are not as affected by electrical storms as are the AM systems.

Specific advantages of FM are the following:

1. The FM receiver is able to discriminate against the pulse type noise generated by such sources as vehicle ignition systems and electrical storms.

2. Two FM stations transmitting simultaneously do not block each other. (Tuning across the broadcast band at night will demonstrate how a comparatively weak AM signal can destroy the intelligibility of a much more powerful station with squeals and whistles.) When two FM stations are received simultaneously, the stronger signal takes over, or "captures" the receiver and communications capability is not destroyed for both. This stronger signal take-over is known as the "capture effect."

Suitability of different spectrum locations for land-mobile transmission

The lower part of the radio frequency spectrum, between 10 kilohertz and 300 megahertz, was the first part to be developed and it was only after World War II that electronic developments made it possible to exploit higher ranges. The useful spectrum has now been extended to about 40 gigahertz. The portion of the spectrum between 10 and 540 kilohertz is used for long-range radiotelegraph stations and radio beacons for ships and aircraft. The AM broadcast band is the section from 535 to 1605 kilohertz in the MF range, and the section between 1605 kilohertz and 25 megahertz is largely used for long-distance radiotelegraph and radio telephone communications, ships at sea, aeronautical navigation, and for international broadcasting.

Between 25 and 890 megahertz are bands for FM and TV broadcasting and a number of safety and special services. The portion from 890 megahertz to 40 gigahertz, spectrum space is used mainly for experimental and developmental work. Figure 4 provides a chart of the spectrum which indicates the uses of the various bands.

Most of the frequencies available for medical use, i.e. for hospitals and ambulances, are in the Public Safety Radio Services. These are primarily land mobile services.* There are allocations for land mobile service in the MF, HF, VHF and UHF bands. However, the two bands of land mobile allocations in the VHF region, commonly referred to as the VHF "Low Band" (30-50 MHz) and the VHF "High Band" (150-175 MHz) together with the 450-470 MHz UHF band contain most of the frequencies available for assignment to the Public Safety Services.

Each band has special characteristics which affect its suitability for land mobile transmissions, and there are trade-offs in regard to range that can be achieved, transmitter power required, penetration in heavily built-up urban areas, noise and interference, and expense. Those frequencies below 3,000 kHz (the VLF, LF and MF bands) are not especially suitable for the land mobile service since efficient transmitting antennas must have rather large dimensions. For example, a quarter wave length vertical antenna for operation at a frequency of 1,000 kHz would be 266 feet high--the same antenna for operation at 150 MHz would be 1.64 feet high, a suitable dimension for vehicular installation.**

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* An explanation of the various services as defined and used by the Federal Communications Commission is found in Appendix B.

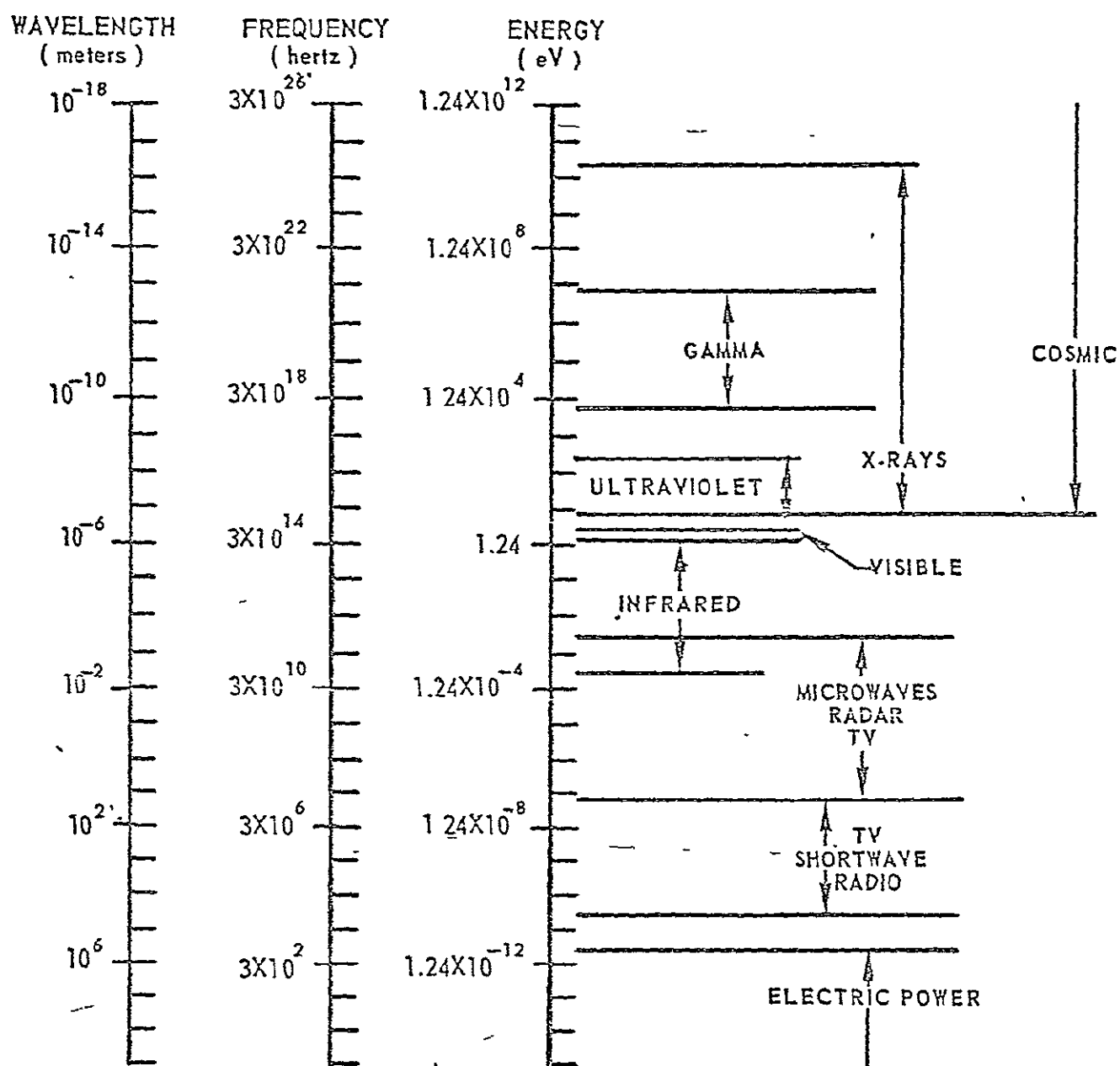
** Antenna dimensions for a particular frequency are directly proportional to wave length. Wave length is related to frequency in this manner:

$$h(\text{wave length}) = \frac{v(\text{velocity of propagation})}{f(\text{frequency in hertz})}$$

Velocity of propagation is 300,000,000 meters/sec or 984,000,000 feet/sec.

Figure 4

THE ELECTROMAGNETIC SPECTRUM



Type of Radiation	Wavelength Range* (meters)	Frequency Range (hertz)	Energy Range (eV)
Electric Power	∞ - 3×10^5	0 - 10^3	0 - 4.1×10^{-11}
Radio Waves	3×10^4 - 3×10^4	10^4 - 10^{12}	4.1×10^{-11} - 4.1×10^{-3}
Infrared	3×10^{-3} - 7.6×10^{-7}	10^{11} - 4×10^{14}	4.1×10^{-4} - 1.6
Visible	7.6×10^{-7} - 3.8×10^{-7}	4×10^{14} - 7.9×10^{14}	1.6 - 3.3
Ultraviolet	3.8×10^{-7} - 3×10^{-9}	7.9×10^{14} - 10^{17}	3.3 - 410
X Rays	1.2×10^{-7} - 4.1×10^{-17}	2.5×10^{15} - 7.3×10^{24}	10 - 3×10^{10}
Gamma Rays	1.5×10^{-17} - 1.2×10^{-13}	2×10^{18} - 2.5×10^{21}	8×10^3 - 10^7
Cosmic Rays	1.2×10^{-7} - ---	2.5×10^{15} - ---	10 - ---

The HF portion of the spectrum has a different characteristic which dictates against its general use in the land mobile service. When ionospheric conditions are favorable, extreme ranges (sometimes in the order of thousands of miles) can be achieved.* Since ionospheric conditions are subject to change due to time of day, time of year, and the level of solar activity, these bursts of extreme range are somewhat unpredictable. When these conditions exist, the land mobile service is plagued by "skip interference."

The primary advantages and disadvantages of the transmission characteristics of the three bands (VHF low and high bands and the UHF band) most used in emergency medical communications systems are presented below. For a more comprehensive discussion of factors governing the selection of suitable frequency bands, see Report of the Advisory Committee for the Land Mobile Radio Services.⁺ It should also be noted that some restrictions can be overcome by proper design. Range limitations in the higher bands, for example, can be overcome by the placement of antennas on a mountain top or a high building, use of outlying receivers or by means of repeater stations.

* The ionosphere consists of several layer-like regions of electrically charged particles at altitudes of 40 to more than 200 miles. These layers act as a reflector of radio waves at frequencies lower than about 10 MHz and as a refracting medium at high frequencies.

⁺ Report of the Advisory Committee for the Land Mobile Radio Services, Federal Communications Commission, U.S. Government Printing Office, Vol 2, Part 1, Washington, D.C. 20402, 1967, pp. 340-355.

Low-Band VHF (30 to 50 MHz)

Advantages:

Greatest range (about 30 miles for a 100-watt transmitter with a 150-foot 3-db gain antenna).

Least power required to transmit for a given range, other conditions being equal.

More suitable for rural areas with dense foliage, since trees and foliage absorb higher frequency transmissions.

Usually better for rough terrain, although in mountainous areas the 150-to 175-MHz band may prove to be more suitable in some respects (better "fill-in" by reflected waves in the shadows of obstructions).*

Disadvantages:

High noise level.

Heavy utilization by a large number of users.

Skip interference which could be a serious handicap in handling emergency messages since it could cause loss of communications at critical times.†

Low reflection off solid barriers prohibits "fill-in" in urban areas (between tall buildings, for example).

High Band VHF (150 to 175 MHz)

Advantages:

Almost total freedom from skip interference.

Shorter antennas can be used, which are more practical for vehicular installation.

Lower noise levels.

Relatively good coverage in metropolitan areas.

* Ibid., p. 352, Radio waves are reflected from the earth and solid structures such as buildings, but the shorter, higher frequency waves reflect better than longer waves.

† Ibid., p. 351.

Disadvantages:

Range somewhat less than can be achieved with low-band frequencies (about 20 miles for a 100-watt transmitter with a 150-foot, 3 db gain antenna).

Car-to-car coverage not as good as in the lower band.

Channel occupancy very heavy, particularly in urban areas.

UHF (450 to 470 MHz)

Advantages:

Good for short-range transmissions.

Least noise level, hence best for high noise environments.

Only channel that can be used for telemetry.

Complete freedom from skip interference.

High gain antennas (which increase radiated power relative to the transmitter power) are very practical

Least channel congestion.

Due to better reflectivity, better distance penetration in dense metropolitan areas between buildings, under bridges, in tunnels, etc. than with lower band frequencies.

Best penetration of building walls, permitting reception and transmission within buildings, and from inside building to a mobile relay.

Disadvantages:

Somewhat less suitable in rural areas, where there is dense foliage or rough terrain.

Limited to shorter range transmissions.

Most power required to transmit for a given range, other conditions being equal.

Car-to-car transmission unreliable unless a mobile relay is used.

Equipment costs somewhat higher.

Microwaves

The frequencies in the higher portion of the UHF range and above are called "microwaves." These have not been much used for the land mobile service. It is more difficult to generate the required transmission power levels at these higher frequencies and costs are higher. However, with mounting pressure for more frequencies, the 900-MHz region of the spectrum is beginning to be developed for mobile uses. According to one report, the 900-MHz is expected to prove nearly as satisfactory for urban communications as the 450-MHz zone, the greatest limiting factor being the five to seven years which is estimated for the development of commercial equipment.*

Microwaves are particularly useful for point-to-point operations. Because of the broad bandwidths of their channels, they have the capability to simultaneously transmit multiple messages and have long been used by the telephone companies and other common carriers for this purpose. There is also a growing use of private microwave for point-to-point operations by the Public Safety, Industrial, and Land Transportation Services. Such systems are most often used by police agencies, petroleum pipelines, turnpikes, railroads, and electric power companies. Some states are now developing microwave "trunking" systems or "backbone" systems covering the entire state. By means of special (but commercially available) equipment at communication centers in such networks, messages between any of the short-range mobile and base stations operating in the VHF or UHF bands can be relayed between each other, no matter where they are located in the state.

* Committee on Telecommunications, National Academy of Engineering, Communications Technology for Urban Improvement, Report to the Department of Housing and Urban Development, National Academy of Engineering, Washington, D.C., June 1971, p. 207.

APPENDIX B

FCC REGULATIONS AND FREQUENCIES AVAILABLE FOR EMERGENCY MEDICAL SERVICES

Radio communications are essential to the functioning of modern society, but the quantity of information that can be transmitted without interference through any given portion of the radio frequency spectrum in any given geographical area is limited. Consequently, this scarce resource must be regulated to insure its use "in the public interest." This Appendix gives a brief description of the Federal Communications Commission (FCC) role in regulating the use of radio frequencies, identifies frequencies available for emergency medical services and indicates some of the restrictions that apply to their use. No attempt has been made to be comprehensive. Rather, the purpose is to present basic considerations involved in setting up a radio operation together with references to sources of further information.

FCC Role

The orderly development of the radio frequency spectrum as a vital national and international resource has necessitated carefully planned allocations to the various radio services. Seven international administrative radio conferences, the first in 1906, have been the principal means by which radio frequency allocations have been controlled internationally. Within the United States, the Federal Communications Commission regulates both foreign and domestic (interstate) communications by radio,

* The reader unfamiliar with basic radio terminology might find a review of Appendix A helpful before addressing this Appendix.

television, wire, cable, and satellite, excluding those of the Federal Government, which are the concern of the Office of Telecommunications Policy of the Executive Office of the President and the Interdepartmental Radio Advisory Committee (IRAC).

Under Section 301 of the Communications Act of 1934, as amended, the operation of any non-government radio* transmitter anywhere within the United States and its possessions requires licensing of the station by the FCC, and in most cases of its operators.+ Excepted are certain low-power devices--wireless microphones, phonographs, oscillators, garage door controls, and other miniature transmitters; however, the operation of these is subject to certain conditions.

FCC functions include:

- o allocating frequency bands for all radio operations, both broadcasting and non-broadcasting (excluding those of the Federal Government);
- o assigning frequencies, power, and call signs to the individual licensees;
- o regulating common carriers engaged in interstate and foreign communications;
- o regulating cable television;
- o monitoring transmissions of all stations that it licenses as well as foreign stations to determine that the stations meet technical requirements, to detect interference and illegal

* Radio is used here in the all-inclusive sense, including television as well as other broadcasting and non-broadcasting uses.

+ However, operators do not need licenses in the Special Emergency Radio Service, frequently used for emergency medical communications.

operations, and to pick up distress signals from planes and ships at sea.

The Commission also sets standards for equipment and approves equipment before it reaches the market. This is done on the basis of data submitted by the manufacturer ("type acceptance"), sufficient in most cases, or on the basis of tests performed by the FCC itself ("type approval").

Frequency Allocations and Assignments

Spectrum space is divided into bands. The Commission allocates each part, or band, to a class of user or type of operation. The frequencies within these bands then become available for specific assignment by the Commission to users eligible for a particular class of radio service. To receive frequency assignments, an applicant must demonstrate his eligibility for a particular service, request the specific frequencies desired, and meet certain conditions to prevent interference with other radio service operators.

The FCC is functionally organized according to the class of user services as shown in Figure 1. Of these classes, the Public Safety Radio Service* is the service of most interest for emergency medical services. Its purpose is to provide radio communications essential for the discharge of non-Federal government functions or for the alleviation of an emergency endangering life or property. Services in this category most used for emergency medical services include: The Special Emergency Radio Service (the most important), the Local Government Radio Service, the Police Radio

* Under the Safety and Special Radio Services Bureau in the FCC.

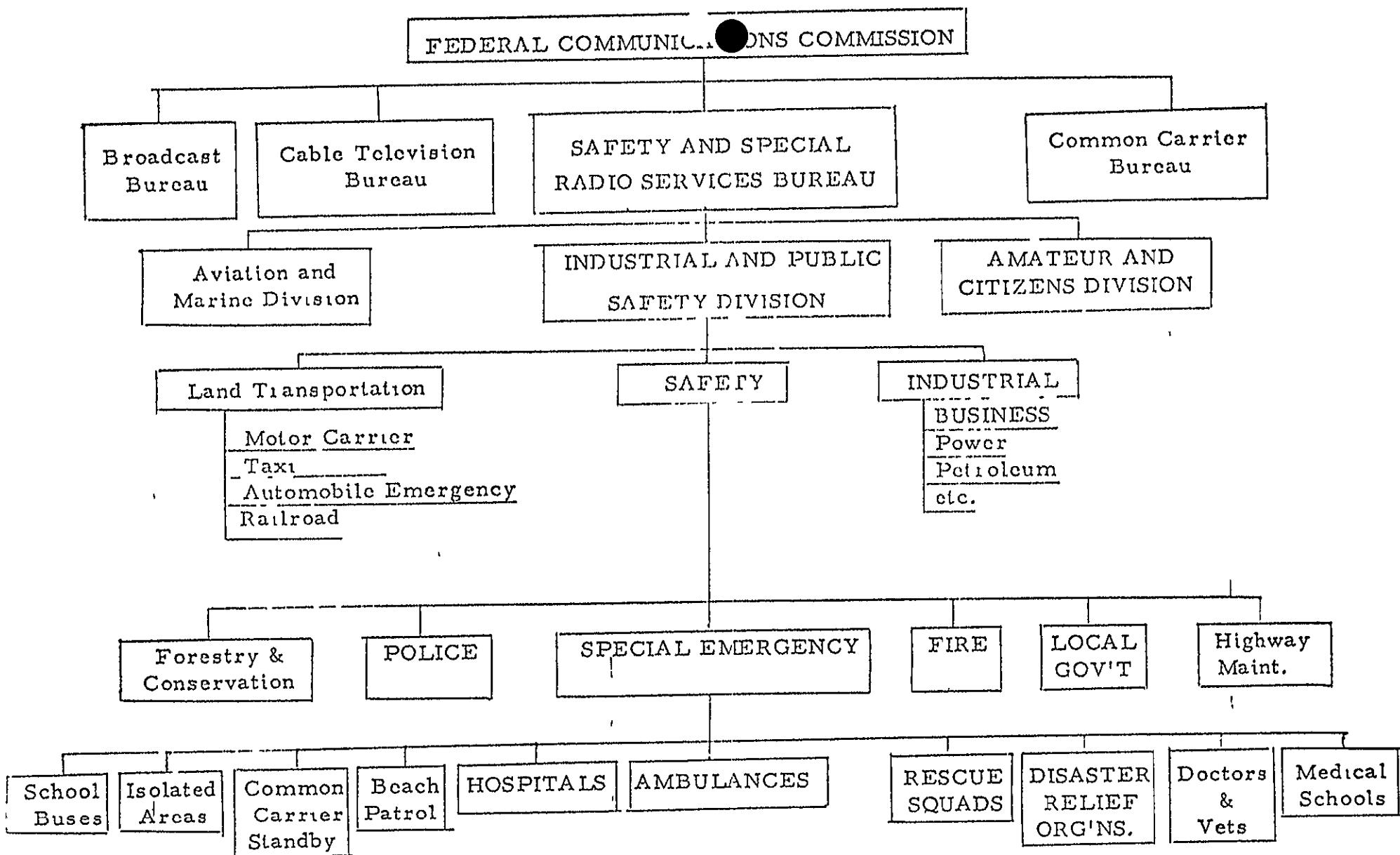
Service, and the Fire Radio Service. Business Radio Frequencies in the Industrial Radio Service are also used.

In allocating frequency bands, the FCC uses, in addition to the user classes noted above, a classification based upon the types of radio operations conducted. These types include fixed, land mobile, marine mobile, aeronautical mobile, and radio navigation, among others. The service most relevant for emergency medical communications is the land mobile service, defined as a "service between base stations and land mobile stations, or between land mobile service stations." Land mobile stations are transmitters and receivers intended for use while in motion on land (for example, in an ambulance), while the base stations are geographically fixed radio stations used to communicate with mobile stations. As an example of this dual classification scheme, both ambulances and taxicabs operate in the land mobile service, the former usually licensed in the Special Emergency Radio Service and the latter in the Land Transportation Radio Service.

Public Safety and Business Radio frequencies are available for assignment to individual land mobile service users in different parts of the spectrum, primarily in the Low and High VHF bands and in the UHF band.* The Public Safety and Business Radio Services also have access to certain fixed station frequencies in various bands.

Frequencies assigned to government radio stations under Executive Order of the President may also be authorized for use of stations in the Public Safety Services if it can be shown that such assignment is necessary for communication with government stations.

* Appendix A contains a discussion of the suitability of each band for certain kinds of transmissions under different conditions.



Note: Services most relevant to emergency medical/communications are capitalized.

Figure 1 - RADIO SERVICES UNDER THE FCC

The Commission allocates frequency bands, assigns individual frequencies and promulgates specific rules and regulations at least in part on the basis of public comment and petitions. Thus, it is the responsibility of interested parties to make their needs and opinions known to the FCC. To facilitate this process, the FCC circulates "Notices of Proposed Rule-Making," invites public comment and may hold public hearings before final decisions are reached.

Complete information on FCC frequency allocations and the rules and regulations governing frequency assignment as well as instructions on how to make applications are to be found in the Federal Communications Commission Rules and Regulations. The sections of most interest for emergency medical communications, contained in Volumes II and V,* include the following:

Volume II

- Part 2 - Frequency Allocations and Radio Treaty Matters. General Rules and Regulations.
- Part 5 - Experimental Radio Services (other than broadcast); includes research and developmental applications.
- Part 15 - Radio Frequency Devices; includes a low-power telemetry devices, for example, those used in hospital wards.
- Part 18 - Industrial, Scientific, and Medical Equipment; includes ultrasonic and medical diathermy equipment.

* Copies of these documents may be purchased from:

Superintendent of Documents
Government Printing Office
Washington, D.C. 20402

Volume V

Part 89 - Public Safety Radio Services; Includes
radio call boxes, Local Government Radio
Service, Fire Radio Service, Police Radio
Service and Special Emergency Radio Service.

Part 91 - Industrial Radio Services;
includes Business Radio Service.

Frequencies Available for Emergency Medical Services

Frequencies for ambulance and hospitals.* Ambulance and hospital communications systems have operated on a wide variety of frequencies -- police frequencies, fire frequencies, local government frequencies, business frequencies, civil defense frequencies, etc. However, there are restrictions on eligibility and types of messages permitted for most of these. Only the Special Emergency frequencies are available for all potential users in emergency medical services, public and private, and for all kinds of medical communications--those having to do with patient care as well as with ambulance dispatch and coordination.

Local Government Radio Service frequencies can be used by any state, city or county hospital, ambulance system or health service, but not by private hospitals or services. Usually no more than two frequencies will be authorized for one applicant unless a legitimate need can be shown for more (Part 89, Subpart E, FCC Rules and Regulations).

Private ambulance services sometimes use Business Radio Service frequencies in the Industrial Radio Service (Part 91, Subpart L, Rules and

* This section is based in part on a summary in a recently published report by the Department of Transportation, Guidelines for Emergency Medical Services Communications. A useful summary is also included in An Emergency Medical System for the State of New York--a report to the Bureau of Emergency Health Services, New York State Department of Health, by Arthur D. Little, Inc. July 1971 pp. IV - 1 to IV - 14.

Regulations). Hospitals, clinics and medical associations are eligible to operate radio stations in this service, along with persons engaged in commercial activities, educational or philanthropic institutions, clergymen, and corporations proposing to furnish nonprofit radio communications services. Public agencies may not use these frequencies, although public hospitals are eligible. All Business Radio Service stations must give priority for channel usage to any station transmitting messages concerning an emergency or immediate danger to life or property.

Police Radio Services and Fire Radio Services frequencies are available only to states, counties, towns and similar governmental entities; stations are authorized to transmit only those communications essential to the official activities of the licensee. These can include ambulance service communications for dispatching, routing and coordination when these services are operated by Police and Fire Departments.

The Department of Transportation report cited in the footnote, page 8, makes the following comment:

A strict interpretation of these requirements would preclude the use of a police or fire frequency for communications between an ambulance and hospital where the message concerns patient care. A message of this type relates to medical matters and not fire or police business. Dispatching, routing, and coordination of ambulance activities over a police frequency have been considered permissible; however, only if the ambulance service is a part of the assigned police or fire department duties. This means that ambulance dispatching communications can probably be carried out on either an SER* frequency by a hospital or independent ambulance service, or on a police or fire frequency, if the service is provided by one of these agencies. It also means that medical communications should be planned for an SER channel.

* Special Emergency Radio

Frequencies in the Special Emergency Radio Service (SERS) are available for use of hospitals, ambulance operators, rescue organizations, physicians and veterinarians, disaster relief organizations (such as the Red Cross), school buses, beach patrols, establishments in isolated areas, local medical societies (that provide members with communications on a nonprofit, cost-sharing basis) and standby facilities for public communications facilities when emergency repair is required. A list of available frequencies in the SERS MF and VHF bands is provided in Table 1.

Most of these frequencies must be shared amongst all of the above classes of users. Of the 13 SERS frequencies in the VHF High Band, however, five have been designated exclusively for the use of hospitals and ambulances that serve them. To use these frequencies, ambulance services must show that they "render coordination and cooperation with a hospital authorized on this frequency" (part 89.525, FCC Rules and Regulations).

A number of communities, regional systems and states have adopted one or two SERS frequencies for use for emergency medical communications throughout the area. Those most commonly used are 155.280 MHz and 155 ³⁴/₁ MHz in the VHF High Band. However, because the rules permit the use of these VHF SERS frequencies for "the rendition of an efficient hospital service" (Part 89.503, FCC Rules and Regulations), these frequencies can also be used for non-emergency hospital communications (e.g. plant security and maintenance functions) as well as for inter-hospital administrative messages.

Frequencies in various bands allocated for fixed station operation are available for assignment to the Special Emergency Radio Service users but on a shared basis with other services. For instance, there are a number of frequencies in the 72.00- to 76.00-MHz region of the spectrum that can

be made available, but with restrictions to prevent interference with other services and with TV channels 4 and 5. There are also frequencies available for fixed station operation in the 450- to 470-MHz band and in the microwave bands above 952 MHz (Part 89.101, FCC Rules and Regulations).

Further, as discussed more fully below, frequencies for ambulance telemetry and related voice communications have recently been made available in the 460-MHz UHF band, as have four frequencies for one-way paging in the VHF low band.

In order to be eligible for the use of SERS frequencies, hospitals must provide services, facilities and beds on a 24-hour basis. Only those communications are permitted that are necessary for efficient hospital service. Ambulance operators and rescue organizations are limited to urgent messages pertaining to the safety of life and property and to the rendition of efficient service. There are also restrictions as to power that may be used, antenna height, type of equipment utilized, and stations with which SERS stations may communicate. For example, base stations are primarily authorized to intercommunicate with SERS mobile stations and secondarily with other Public Safety Radio Stations. (Parts 89.11 and 98.521, FCC Rules and Regulations).

In general, hospitals and ambulance operators licensed in the SERS are allowed only one base station and the number of vehicular mobile stations cannot exceed the number of vehicles used in the service. Additional hand-carried or back-pack stations are permissible. It should also be noted that licensees in either the Public Safety or Business Radio services are permitted to engage in a cooperative sharing of facilities (e.g. base station) on a non-profit, cost sharing basis.

RACE AND MONITOR FREQUENCIES					
FREQUENCIES AVAILABLE TO ALL SPECIAL EMERGENCY SERVICES INCLUDING HOSPITALS AND AMBULANCES			LIMITATIONS		
			Current		Proposed
Band	Frequency	Other services sharing this frequency	75-mile, 30 kHz Rule applies (see page 14 of this Appendix)	Developmental Use only - 40-mile, 30-kHz Rule applies (see page 15 of this Appendix)	40-mile 15-kHz Rule would apply if proposal in Docket No. 19523 is adopted (see page 15 of this Appendix)
MF	2726 kHz 3201	State Guard			
VHF - Low Band	33.02 MHz	Highway Maint.			
	33.04				
	33.06	Highway Maint.			
	33.08				
	33.10	Highway Maint.			
	37.90	Highway Maint.			
	37.92	Highway Maint.			
	37.98	Highway Maint.			
	45.02		X		
	45.06		X		
	46.00		X		
	46.04		X		
	47.40				
	47.50				
	47.54				
	47.58				
47.62					
47.66					
VHF - High Band	155.100 MHz		X		-X
	155.175			X	X
	155.205			X	X
	155.220		X		
	155.235			X	X
	155.255			X	X
	155.260		X		
	155.265			X	X
FREQUENCIES AVAILABLE ONLY TO HOSPITALS AND AMBULANCES RENDERING COOPERATION TO HOSPITALS ASSIGNED THESE FREQUENCIES					
VHF High Band	155.325 MHz			X	X
	155.340		X	X	
	155.355			X	X
	155.355			X	X
	155.400		X		X
VHF Low Band	35.04 MHz		Available only to hospitals and ambulances for one-way paging to mobile receivers.		
	35.08				
	43.04				
	43.68				
MISCELLANEOUS					
47.42 MHz		Available ONLY to SERS base and mobile stations in National organizations established for disaster relief purposes			
72.00-76.00 MHz		Available for SERS Operational Fixed Stations, shared with many other services. See Part 1, FCC Rules and Regulations for specific frequencies available in this band.			

Table 1
Frequencies Allocated to the Special Emergency Radio Service
in the MF and VHF Bands

Frequency Coordination. Applicants for spectrum space are often required to coordinate frequency use with other users in the area. In the case of Public Safety Radio Services, except Special Emergency Radio Services, applicants requesting frequencies below 470 MHz must submit a report based on a field study showing the degree of probable interference with existing stations within 75 miles of the proposed station that operate on the same channel. Approval must also be obtained from a frequency advisory committee "recommending the specified frequency which in the opinion of the committee will result in the least amount of interference to existing stations operating in the particular area." (Part 89.15, Vol. V, Rules and Regulations). Frequency advisory committees are voluntary organizations composed of representatives of those in the community eligible to use radio frequencies in a particular radio service.

As noted above, the SERS frequencies are excluded from these coordination requirements, however, applicants for Local Government, Police or Fire Radio Service frequencies for ambulance communications are governed by them.

Within the SERS, there are no frequency coordination rules to avoid interference between SERS stations. However, applicants applying for certain SERS frequencies in the VHF bands (33-156 MHz) must coordinate with stations in the Police, Fire and Local Government services operating nearby. The requirements are contained in two rules.

The 75-mile, 30 kHz Rule applies to nine SERS frequencies (Table 1). These frequencies are available for assignment provided that:

a) the application is accompanied by a written and signed statement that licensees of all stations, excluding Special Emergency stations, located within a radius of 75 miles of the proposed location and authorized

to operate on a frequency 30 kHz or less removed have concurred with such assignment, or

b) an engineering report is submitted indicating that harmful interference to the operation of such existing stations will not be caused.

The 40-mile, 30 kHz Rule applies to eight VHF frequencies (Table 1) designated for developmental operations only, and requires applicants to show:

a) the proposed location is at least 40 miles from the station location of each other station, operating on frequencies 30kHz or less removed, except Special Emergency licensees, and

b) the requirements of the 75-mile, 30-kHz restriction above are also met and existing license holders notified of the application.

The FCC is currently reviewing these rules and has proposed a revision (Docket No. 19523, June 14, 1972). The 75-mile, 30-kHz limitation would be deleted altogether. Seven of the nine frequencies to which it now applies would no longer be subject to any special limitation of this kind. Applications for the other two and for the eight frequencies formerly governed by the 40-mile, 30-kHz limitation, would have to be accompanied by:

a) a report based on a field study indicating the degree of probable interference to existing base stations in radio services other than the SERS which operate within 15 kHz and are located from 10 to 35 miles from the proposed base station, and

b) a signed statement that the licensees of all such stations are aware of the application.

The new proposal will prohibit new stations less than 10 miles from existing base stations. It will also free for regular (rather than (developmental) service the eight 40-mile, 30 kHz frequencies: Final

comments to the Commission on the proposal were due in September, 1972.

Frequencies for ambulance telemetry. Until a short time ago, there were no frequencies on which routine ambulance telemetry was permitted. However, the FCC did grant temporary developmental licenses, authorizing telemetry on certain frequencies in the VHF and UHF bands. After much deliberation, a ruling was made in March, 1972, designating seven new frequency pairs in the 460-MHz region of the UHF band as available for permanent assignment for ambulance telemetry and the dispatch of telemetry-equipped vehicles. Henceforth, no new assignments will be made in the VHF High Band for ambulance telemetry. The frequency pairs are listed in Table 2.

As shown in the table, two base/mobile pairs are intended primarily for dispatch purposes and five for telemetry. Provisions are also included to permit the ambulance mobile transmitter to serve as a telemetry relay station between portable telemetry or voice units and hospitals.

A key phrase regarding the dispatch of vehicles in this Ruling states that the dispatch and dispatch response frequencies are assignable to "...dispatch ambulances and personnel operating bio-medical telemetry units in this service under an area-wide communications plan." Thus, the Commission has reserved these frequencies for use only by telemetry-equipped ambulance services. Further, since they are the only available frequencies for telemetry, the area-wide coordination requirement will provide an incentive for the development of rational regional EMS communications plans. However, the Ruling poses two problems to EMS communication systems planners:

- (1) The Ruling does not state whether all or only some of the centrally dispatched vehicles must be telemetry equipped. Many ambulance services currently plan to have both telemetry and non-telemetry equipped vehicles in operation. A strict interpretation of the Ruling would dictate that the latter be dispatched on other frequencies (i.e. VHF) than those listed above.

Table 2 - UHF Ambulance Telemetry Frequencies

Frequency Pairs (MHz)		Radio Services in Which Available	Notes
Base or Mobile	Mobile Only	F=Fire LG=Local Gov't. SER=Special Emergency	
460 525		F LC, SER	(1)
	465 525	SER	(2)
460.550		F LG SER	(1)
	465.550	SER	(2)
463.000			(3)
	468.000	SER	(4)
463.025			(3)
	468 025	SER	(4)
463.050			(3)
	468.050	SER	(4)
463.075			(3)
	468 075	SER	(4)
463.100			(3)
	468.100	SER	(4)

Notes

- (1) Assignable only for central dispatching of ambulance telemetry systems under an area-wide communication plan for coordinated use of telemetry frequencies.
- (2) Assignable for mobile dispatch response by ambulances operating telemetry under a centrally dispatched area-wide communications plan. May also be assignable on a secondary basis for telemetry or telemetry relay.
- (3) Assignable to hospitals for communication with telemetry-equipped vehicles and personnel equipped with telemetry (e. g. portable units). Also available for portable telemetry and associated voice transmissions.
- (4) Assignable for mobile telemetry transmission from ambulances or portable units. Also available on a secondary basis for telemetry-related voice transmission. Mobile stations on this frequency can be used as a relay station between portable units and medical care facilities.

- (2) Some areas are developing and equipping new ambulance services now with the intent to add telemetry at a later date. It is not clear that such systems would be permitted to dispatch vehicles on these frequencies prior to operating telemetry.

Both problems affect equipment economics, the first requiring duplicate base-station transmitters and differing types of mobile equipment. The second might require the purchase of VHF equipment which would have to be replaced by UHF equipment before normal retirement. Applicants who face these problems should discuss them with the Commission to determine the best means of presenting their application for frequency assignments.

Frequencies for short-range, low-power telemetry. Low-power telemetry devices have been used in hospitals for continuous monitoring of heart action in patients recovering from surgery or heart attacks and in newborn infants by means of a transmitter attached to the patient that sends the signal to a nearby receiver. A portable device of this kind is also needed for monitoring a patient before he is placed in an ambulance.

As noted above, the five base-designated SERS frequencies in the 460-MHz band may be used for this purpose. Other frequencies in the 10- to 90-kHz, 510- to 1600-kHz, and 26.97- to 27.27-MHz bands as well as in the VHF and UHF bands may also be used.

Part 15, Subpart E, FCC Rules and Regulations delineates the power limits, other requirements and frequencies authorized for these devices, which do not require station licenses or frequency assignment by the Commission. As of March 8, 1972, the rules have been revised for the operation of low-power telemetering devices and wireless microphones above 70 MHz.* Under the new

* "Report and Order," Docket No. 19231, amending Part 15.211 FCC Rules and Regulations.

rules, the operation of low-power biomedical telemetry devices, such as heart-monitoring systems, are excluded from a duty cycle requirement that transmissions be no longer than one second and that there be a silent period between transmissions of not less than thirty seconds.

Biomedical telemetry equipment may also be licensed for operation in the Business Radio Service (Part 91, FCC Rules and Regulations).

Frequencies for Radio Call Boxes. Radio call boxes such as those stationed along certain highways or used as streetside fire alarms in cities fall under the Public Safety Radio Service (Part 89.102, FCC Rules and Regulations).

Frequencies in the Local Government Radio Service may be assigned for the operation of radio call boxes, to be used by the public to request fire, police, ambulance, road service, and other emergency assistance. Some 68 different frequencies in the 72- to 76-MHz band may be assigned for this purpose. They are limited to non-voice, short signals and are subject to certain other specifications as stated in Part 89.102.

Four sets of paired frequencies have also been designated for call box operation in the 450-MHz band, solely for call box systems installed on limited access highways. For these, however, voice as well as non-voice signalling are authorized. These frequencies may be also assigned for developmental operation for highway safety communication programs designed to provide radio communication directly with motorists.

Frequencies for paging. Frequencies for paging operations may be assigned under the Special Emergency Radio Service (Part 89, Subpart P, FCC Rules and Regulations).

From the many frequencies available in the Business Radio Service, three in the 150-MHz VHF High Band and nine in the 460-MHz UHF Band have

recently been allocated to the Special Emergency Radio Service for base station one-way paging transmissions to mobile receivers ("First Report and Order," FCC Docket No. 19327, June 14, 1972). Because paging has created interference problems in the mobile service, the Commission is strongly encouraging the use of these specific paging frequencies.

Two-way paging systems that allow for response by the paged person are classified as regular land-mobile operations and must conform to land mobile requirements of the services in which frequencies are assigned.

Other Radio Services

There are three other radio services that at times might be utilized for emergency medical communications.

The Citizens Radio Service (Part 95, FCC Rules and Regulations) provides short-range, low power two-way radio communications at relatively low cost for business and personal activities. Priority, however, must be given to emergency communications concerning the safety of life and property. Most citizens band radios are licensed as "Class D" mobile units, although these units can be operated at fixed locations as well. Twenty-three channels (identified in this service as Channels 1 - 23) have been allocated for Class D use in the 26.96 - 27.23 Hz band. Only seven of these channels may be used for communication between stations of different licensees, (inter-station communications). Twenty-two channels, including the seven open to inter-station communications, are available for transmissions between units of the same station (intra-station communications). The remaining one channel, (Channel 9, 27.065 MHz), may be used only for:

- a) emergency communications involving the immediate safety of life of individuals or the immediate protection of property, or
- b) communications necessary to render aid to a traveling motorist.

A voluntary organization, REACT (Radio Emergency Action Communication Team), has been formed to organize Channel 9 users to report emergencies and to render assistance to motorists. REACT teams are prepared to provide supplementary communications in any emergency. Effective local two-way radio communications have proved valuable when normal telephone communications are interrupted because of fire, blizzard, earthquake, flood, hurricane, tornado, or other disasters.

The Disaster Communications Service (Part 99, FCC Rules and Regulations) is designed to provide "essential communications incident to or in connection with disasters or other incidents which involve loss of communications facilities normally available, or which require temporary establishment of communication facilities beyond those normally available." Stations licensed under this service must be a part of an organized disaster communications network, planned and operated by "any responsible local group or groups that may be in a position to provide such service" (Part 99.9 FCC Rules and Regulations). The stations may be used only during bona fide drills and tests or during an impending or actual disaster. Shared with the Industrial Radio Service, fourteen frequencies are available for assignment, all in the Medium Frequency Band, 1750 - 1800 kHz. Eight are reserved for telegraphy only, five for voice transmission (amplitude modulated), and one, designated the "Scene of Disaster Channel (1761.5 kHz), is authorized for both types of transmissions. It may be used only by stations actually in the disaster area or by stations communicating with them.

Because the frequency band allocated to the Disaster Communications Service is much lower than the VHF or UHF bands used by most Public Safety Radio Services, vehicles and facilities used in daily emergency medical service activities will rarely be equipped to communicate on these disaster frequencies.

The Amateur Radio Service is a service for persons interested in radio technique "solely with a personal aim and without pecuniary interests" (Part 97, FCC Rules and Regulations). Frequency allocations for this service span a wide range from 1800 kHz to well above 40,000 MHz.

The Amateur Service has provisions for the declaration of a "general state of communications emergency" (Part 97.107, FCC Rules and Regulations) by the Commission. In this event, emergency segments within the allocated amateur bands are designated and transmissions within those band segments in the geographic areas affected are limited to emergency communications.

Within the Amateur Service, a special Radio Amateur Civil Emergency Service (RACES) has been established (Part 97, Subpart F, FCC Rules and Regulations). This service permits the operation of local amateur emergency communications networks to provide communications during civil emergencies. The network must be planned and operated under the direction of duly authorized civil defense authorities.

APPENDIX C

SHORT DESCRIPTIONS OF COMMUNICATIONS HARDWARE

This Appendix provides short descriptions of equipment and features incorporated into communications systems. They are intended to provide a simple functional understanding of the technical terminology used in this report.

Special Telephone Lines

In addition to the standard telephone service, three special telephone links are often used in EIS communications:

Hot Lines

A hot line is one where a large number of stations are on a party-type circuit and a line is always alive and activated. When the phones are on the hook at each station, the monitoring is provided by a loud speaker. When one station wishes to call other stations on the net, he picks up his phone and calls and this call is put out on the loud speaker at each of the other stations. Thus, two parties or all parties can engage in a conversation. Such a hot line circuit of course requires that someone be at the monitoring station at all times to monitor the loud speaker or alternately that an alarm buzzer be placed at each station to summon someone to listen to the message. This type of hot line is quite common in the military command system and is only justified when there is a fairly heavy volume of traffic. Being a continually energized line, it is the most expensive of all types of lines.

Dedicated Lines

With a dedicated line, or red line, one has only to pick up the phone and the call is made automatically to the control center. There is no dial on such a red dedicated phone. If there are 20 such dedicated substations,

any of the 20 can go to the center merely by picking up the phone but to talk to another station from that they must first go to the center and ask to be connected. The center switchboard can then merely cross-patch it with a conventional cable plug-in. Such a system can then also provide for a party line conversation merely by asking the center to connect them with the number of stations desired. This system is cheaper than the hot line system and has the advantage that one has only to pick up a phone in order to go into central and does not have to dial. At the same time, you do not have to have a constant monitor on a speaker as the center will ring you merely by plugging in and you pick up the phone and are in contact. This system is cheaper than the hot line system.

Restricted Lines

A restricted phone system is simply an unlisted number type system. Only those with a need to know have the numbers of the phones and in each case you must dial. The advantage of the restricted system is that you can prevent unauthorized parties from tying up the phone circuit. It is cheaper than either the hot line system or the dedicated system. A typical example would be the installation of an unlisted phone with a distinctive color in the emergency department with only the members of the EMS system having the number. It has a disadvantage that you cannot patch a number of phones together into a party line.

Radio Stations

Base Stations

Base stations are transmitters and receivers located at fixed sites such as hospitals, dispatching centers, and the like. Often the base transmitter and its antenna tower are located remotely from the point of their control. For example, a dispatcher may be located in a communications center with his control console connected by landlines (wire) to a transmitter placed on a distant hill.

Mobile and Portable Stations

Mobile stations are transmitters and receivers intended for use while in motion (e.g. in an ambulance). They may, of course, also be used when the carrying vehicle is stopped. Portable stations can be hand-carried, for instance, from an ambulance to the side of a patient.

Repeater Stations

Repeater stations are stations, either fixed or mobile, that relay a transmitted signal, generally from a low-powered, nearby transmitter to a distant receiver point.

Squelch Systems

Audio Squelch and Falsing

To the listener of a receiver used intermittently (e.g., an ambulance attendant monitoring his dispatching radio), the presence of continual static and background noise between legitimate transmissions can be very annoying. To overcome this problem, an "audio" squelch circuit may be employed in the

* For further information, see Appendixes A and B which present the basic principles of radio communication and role of the Federal Communications Commission in regulating radio use, respectively.

receiver. This circuit, in effect, keeps the audio (sound) circuits of the receiver turned off when no transmissions on the channel to which the receiver is tuned are taking place. It also automatically turns on the receiver's audio circuit instantaneously when a transmission begins and keeps it on throughout the transmission. The system operates rapidly enough that no loss of voice information occurs at the beginning of the transmission. However, adjacent channel transmissions (15 or 30 kHz either side of the desired frequency) can also actuate a receiver's squelch circuit and turn the audio circuit on when, in fact, no desired transmission is taking place. This is known as "falsing."

Tone-Coded Squelch

The simple audio squelch circuit responds to any transmissions received, whether or not it is of interest to a particular listener. However, within a particular service area, a single radio frequency may be shared by a number of users. If each receiver responded to every transmission made, most of which were of no interest to the user of one particular receiver (e.g., a dispatcher communicating with a fleet of ambulances), the continual "chatter" on the channel could be of considerable "botherance."^{*}

The "tone-coded" squelch circuit was developed to eliminate botherance. The tone-coded squelch circuit in the receiver is activated by a particular low frequency audio tone incorporated in the transmitted signal. If the

^{*} Botherance is defined as the effect of undesired signals when no desired signal is being received--undesired signals received simultaneously with desired signals constitute "co-channel" interference.

signal includes the correct tone frequency for a given receiver, that receiver's audio circuits are turned on permitting the transmission to be heard. About 30 different audio tones can be incorporated into the standard bandwidth of the VHF channels used in mobile radio services. Thus, with proper equipment, one transmitter can selectively call each of thirty groups of one or more receivers although all are tuned to the same frequency.

Digital-Encoded or Dial-Encoded Squelch

Another technique for the same purpose employs a train of coded pulses in the transmitted signal to activate the selected receiver which contains special decoding circuitry. This digital system is usually controlled at the transmitter by a digital encoder which resembles a standard telephone dial, and is called a "digital-encoded" or "dial-encoded" squelch system. Since two or three numbers are usually dialed, far more than 30 separate receiver "addresses" can be accommodated on a digitally-encoded system.

Such squelch circuits have several trade names such as "Channel Guard" and "Private Line." It must be noted, however, that they do not provide a private line nor do they guard any channel. While permitting a transmitter to select only certain receivers, thus reducing "botherance," the fact remains that only one transmission can be made at a time. In this respect, tone-coded and digital squelch systems operate much as a "party line" in rural telephone systems. In fact, improper use of squelch systems can increase interference. Because his tone-encoded or dial-encoded squelch has muted the receiver, an operator may assume he has a clear channel. If he proceeds to transmit without first listening (with the squelch "off") to determine that the channel is clear, he can be guilty of creating co-channel interference.

Transmission Modes

Simplex Systems

Radio systems having more than one transmitter operate in simplex, half-duplex, or full-duplex modes. In a simplex system, all transmitters and receivers are tuned to one frequency. Only one transmission can occur at any given time, but all stations can communicate with each other (Fig. 1a).

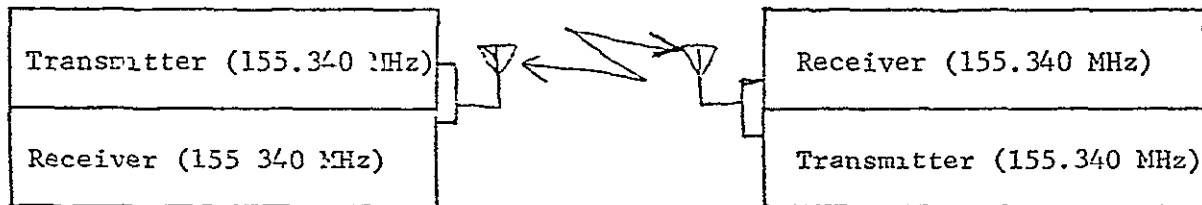
Half-Duplex Systems^{*}

The half-duplex system is generally used, as in dispatching, for a base station communicating with a group of mobile stations; the base station transmits on one frequency and all of the mobile stations on a close but different frequency (Fig. 1b). As in a simplex system, the transmitter-receiver sets (transceivers) are so designed in the half-duplex system that lifting a microphone from its cradle (or pressing a "talk" button) disables the receiving portion of the calling transceiver and activates the squelch circuit of the called receiver(s). Thus, although two frequencies are used, only one transmission (either to or from a base station) can occur at a time because the calling receiver is muted. Further, in the half-duplex system mobile units cannot communicate with each other. It has the advantage over a simplex system of reducing "botherance" since the mobile units do not hear each other's transmissions. It also has value in crowded urban areas where many fleets of mobile users (e.g., police, taxi, ambulance, public services) are all using crowded VHF spectrum space.

^{*}Sometimes called a "two-frequency simplex" system.

BASE STATION

MOBILE UNIT



(Using an example in the VHF High Band)

Figure 1a - SIMPLEX TRANSMISSION
(Only one transmission at a time)

BASE STATION

MOBILE UNIT

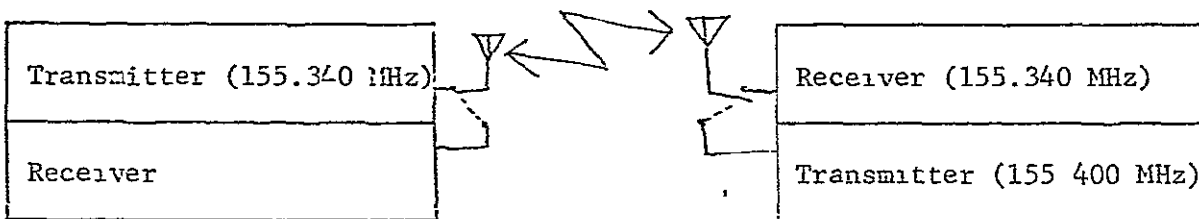
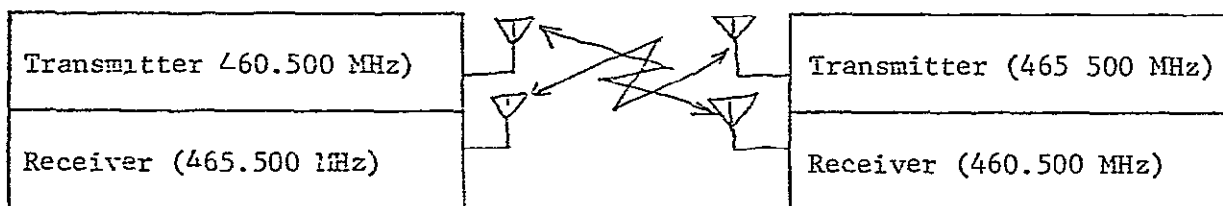


Figure 1b - HALF-DUPLEX TRANSMISSION
(Only one transmission at a time)

BASE STATION

MOBILE UNIT



(Using an example in the UHF Band assigned for the dispatch of telemetry-equipped units)

Figure 1c - FULL DUPLEX TRANSMISSION
(Simultaneous two-way transmission)

Full-Duplex Systems

In the full-duplex mode (Fig. 1c), transmitters and receivers at a given location operate on separate frequencies spaced far enough apart that mutual interference does not result. As opposed to the simplex or half-duplex systems, the full-duplex mode permits both the transmitter and the receiver at a station to operate simultaneously, thus allowing simultaneous transmissions on both frequencies. In general, it is the costliest of the three types.*

Telemetry

The telemetry of physiological signals or patient data involves the transmission of such information over a radio link followed by a decoding and presentation (e.g., on an oscilloscope or on a paper tape) at the receiving site. This is accomplished by modulating the radio signal with an analog (continuous) waveform (e.g. electrocardiogram) or by using pulsed digital signals which can be used, for example, to drive remote teletypewriters.

Paging

Other uses of non-voice radio include signaling functions such as those used in paging systems and highway call boxes. In paging, the receiver is a small portable unit selectively addressed by a tone-coded or digital-encoded squelch system; the simplest merely emits an audible tone to notify the wearer of the page. More sophisticated paging systems allow one-way voice communication (from the paging center to the person paged), others incorporate

* A complete discussion of the three systems, their interference characteristics, and methods for choosing one in any intended application are given in Report of the Advisory Committee for the Land Mobile Radio Services, Federal Communications Commission, Vol. 2, Part 1, U.S. Government Printing Office, Washington, D.C. 20402; pp. 195-279.

a signalling transmitter in the paging device to allow the recipient of the page to immediately acknowledge receipt by radio. More generally, the page is acknowledged by a call-back on a telephone or by the paged person reporting to a specific location.

Call Boxes

Non-voice call boxes (for example, those deployed along some highways) cause a digital pulse-coded signal to be transmitted to a central receiving site. Equipment at the center decodes the pulses to identify the specific call box (thus determining location). In some systems, the nature of the emergency (e.g. fire, police, medical) is also incorporated into the coded pulses; the call boxes having several pushbuttons so marked.

Patching

Patching is a method whereby a radio and a telephone link, two radio links operating on different frequencies or two telephones are tied together at a central location to permit direct communication between the two endpoints.

Telephone-Telephone Patching

Telephone-telephone patching is accomplished in the same way that an operator on a typical telephone switchboard connects a calling party with a called party by plugging in appropriate cables (called "patchcords") or by using other, more sophisticated telephone switching equipment. Such patching might be used when a dispatcher desires to connect a physician at home with a caller on an emergency department hot line.

Radio-Telephone Patching

Radio-telephone patching is a similar technique whereby a dispatcher can patch together his radio transmitter/receiver and a telephone line to

place the user of a mobile radio unit in direct communication with a party reached by telephone. A central dispatcher, for example, connected by radio to an ambulance and by dedicated hot line telephone to the emergency suite of a hospital can thus place the ambulance attendant in direct contact with the hospital staff. Special equipment commercially available enables this to be done by simple switching or by patchcords.

Radio-Radio Patching

This is used when it is desirable to place two radio units in contact that are operating on different frequencies, for example, an ambulance radio transmitting and receiving in the UHF band and a police cruiser using the VHF band. Again, this can be simply accomplished with special equipment at a central dispatching point where transmissions from both vehicles are being received. In this case, the dispatching center serves as a two-way repeater station between the vehicles.

Microwave Trunking Systems

A "trunking" system utilizes several (or many) communications channels between two or more points that are shared by many users. The users connected by such a network outnumber the channels available; trunking systems are used where not all users desire access to a channel simultaneously. As calls are initiated between users, they are automatically assigned to any available channel. Only when all channels are in use would a user encounter a "busy" condition.

Because the broad bandwidths in the microwave region of the spectrum (above 900 MHz) permit many voice channels, microwave can effectively be used for trunking. Equipment for this is readily available; in fact, the telephone companies use it extensively and routinely in their public long-distance telephone operations.

Several EMS systems under development* use microwave trunking to provide communications between the various elements of the system. A backbone microwave loop, composed of microwave transmitters and receivers, provide a complete trunking circuit covering the entire geographic area served by the EMS system. Hospitals, dispatcher, ambulances and others are connected to the trunking net through telephone patching, dedicated lines to the microwave transmitters, or by intermediate radio links on VHF or UHF frequencies.

The latter is accomplished by incorporating, for example, VHF or UHF transmitters and receivers on each microwave antenna tower. Signals to and from mobile units on VHF or UHF channels are automatically fed into the microwave net at the tower nearest the mobile unit, the microwave circuits then being used to carry the transmissions a greater distance. Such systems also can use tone-encoded and/or digital-encoded squelch techniques so that a dispatcher, using the backbone net and the VHF-UHF connecting links, can address particular stations and units in the system.

* For example: San Diego County, and the Ohio Valley Health Services Foundation (Athens, Ohio), and the State of Nebraska.